VOLUME 15 NUMBER 4

Food-Drug-Cosmetic Law Journal

APRIL • 1960

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FOOD ADDITIVES

FDA Answers to Questions Submitted at 1959 Joint National Conference of Food and Drug Administration and The Food Law Institute, Inc.

Articles . . . . . JOHN L. HARVEY
. . . GEORGE P. LARRICK
. . . J. KENNETH KIRK

See Table of Contents for Articles in This Issue

A COMMERCE CLEARING HOUSE PUBLICATION

PUBLISHED IN ASSOCIATION WITH THE FOOD LAW INSTITUTE, INC.

The editorial policy of this JOURNAL is to record the progress of the law in the field of food, drugs and cosmetics, and to provide a constructive discussion of it, according to the highest professional standards. The FOOD DRUG COSMETIC LAW JOURNAL is the only forum for current discussion of such law and it renders an important public service, for it is an invaluable means (1) to create a better knowledge and understanding of food, drug and cosmetic law, (2) to promote its due operation and development and thus (3) to effectuate its great remedial purposes. In short: While this law receives normal legal, administrative and judicial consideration, there remains a basic need for its appropriate study as a fundamental law of the land; the JOURNAL is designed to satisfy that need. The editorial policy also is to allow frank discussion of food-drug-cosmetic issues. The views stated are those of the contributors and not necessarily those of the publishers. On this basis, contributions and comments are invited.

The FOOD DRUG COSMETIC LAW JOURNAL is published monthly by Commerce Clearing House, Inc. Subscription price: $15 per year, including a handsome binder to hold one year's issues. Single copies are $1.50 each. Editorial and business offices, 4025 W. Peterson Ave., Chicago 46, Ill. Printed in United States of America.

April, 1960

Volume 15 • Number 4

Second-class postage paid at Chicago, Illinois.

FOOD DRUG COSMETIC LAW JOURNAL

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Printed in United States of America

FOOD DRUG COSMETIC LAW JOURNAL

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REPORTS

TO THE READER

About the Authors

Featured in this April JOURNAL are answers by representatives of the United States Food and Drug Administration to questions submitted at sessions of the November, 1959 joint national conference sponsored by the FDA and The Food Law Institute, Inc., of New York City. Formal papers from the conference, which discussed food additives and other major food problems under the Federal Food, Drug, and Cosmetic Act, were published in JOURNAL issues for December, 1959, and January, 1960.

The answers to the questions reflect only the views of the FDA people who prepared the replies, and not necessarily the views of all the participants in the conference.

Organizations cooperating in presenting the conference were The Food Protection Committee of the National Research Council; the Food Additives Committee of the Manufacturing Chemists' Association; the Food Additives Committee of the Institute of Food Technologists; The Nutrition Foundation, Inc.; and The Packaging Institute, Inc.

A number of papers derived from speeches by FDA officials also appear in this issue. One is by **John L. Harvey,** Deputy Commissioner of Food and Drugs; two by **J. Kenneth Kirk,** an assistant to the Commissioner; and the fourth by Commissioner of Food and Drugs **George P. Larrick.**

Mr. Harvey's paper—"What Can Industry Do to Help Solve Problems of Antibiotics and Insecticides?"—was delivered before the Milk Industry Foundation, at Miami Beach, Florida, on October 8, 1959. In it he briefly outlines the inquiries and investigations which FDA has made concerning these problems and then goes on to discuss what his agency is doing; what it intends to do; and what, in his opinion, the industry can do to help in solution of the difficulties.

The first of Mr. Kirk's contributions deals with safety of packaging materials. Speaking before the Twenty-first Annual Packaging Institute in New York City last November 18, he urged industry representatives in his audience to discuss their problems with FDA as they go along. Emphasizing that the Administration wants to be as helpful as possible, he pointed out that unless the packaging people have a lot of experience in the foods field, FDA would advise against going ahead with expensive testing programs without prior discussion with the government's technical men. His second article comes from an address on additives legislation affecting foods and cosmetics, presented at the Fatty Acid Producers' Council on January 20 at New York City.

Commissioner Larrick's summary of the status of food-additives control was delivered before The Food Group, in Washington, D. C., on January 27.

Also in this JOURNAL is the feature "Foreign Law Comment," written by **Julius G. Zimmerman,** an attorney, of New York City. Dr. Zimmerman is our editor of foreign law.

WASHINGTON-

ACTION AND NEWS

In the Food and Drug Administration

Orange Juice and Orange-Juice Products.—The Food and Drug Administration, on April 14, issued a stay of its March 1, 1960 order establishing definitions and standards of identity for orange juice and orange-juice products.

The order as published in the *Federal Register* gave notice of a provision of law allowing 30 days for the filing of objections by parties adversely affected. John L. Harvey, Deputy Commissioner of Food and Drugs, said a large number of objections were received, several of which presented reasonable grounds in support of requests for a public hearing. Under the circumstances, a public hearing is mandatory and the standards will not become effective on June 1, 1960, as originally contemplated, Mr. Harvey said.

Regarding the probable date of final resolution of the matter, Mr. Harvey made the following statement:

"Important issues are involved which can be resolved only after consideration of what is likely to be rather extensive evidence. It is therefore apparent that no standards based on the testimony at a hearing could be made effective before the spring of 1961. From the nature of some of the objections, it is anticipated that the effective date of the order which will issue following the hearing will have to be determined on the basis of testimony at that hearing."

It was noted that, when determined, the issues for the hearing would be announced in the *Federal Register*, at which time the date and place of the hearing would also be designated.

Mint-Flavored Pineapple.—Mint flavoring for canned pineapple would be permitted under a proposed change in the federal identity standard for this food, the Food and Drug Administration announced on March 28.

The Administration also invited written comments from all interested persons as to whether the standard should provide for the addition of spice, vinegar, and flavoring other than artificial. Such optional flavoring ingredients are already permitted, the agency pointed out, under the identity standards for most other canned fruits. Under both proposals, the label of canned pineapple would be required to state the use of any optional flavoring ingredient.

Sixty days are allowed for the comments, which will be considered by the Commissioner of Food and Drugs in deciding if the proposals promote honesty and fair dealing in the consumer interest, as required by law.

The proposals were published in the March 25 *Federal Register*.

Color Delisting Order Upheld.—On March 7, the United States Supreme Court upheld an order of the Secretary of Health, Education, and Welfare delisting coal-tar colors Yellows Nos. 3 and 4 for use in margarine and butter. Thus, the order banning any future use of these colors in foods went into effect on April 6.

(Continued on page 285)

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FDA Answers to Questions Submitted at Conference Cosponsored by Administration and FLI at Washington on November 16-17, 1959

During the Joint National Conference of the United States Food and Drug Administration and The Food Law Institute, Inc., Written Questions Were Submitted for Discussion at an Informal Panel Session. (For Papers Presented During the Earlier Sessions, See the December, 1959 and January, 1960 Issues of the *Journal*)

Cancer

Question.—In the Delaney clause, what does the phrase "is found to induce cancer" mean? *Answer.*—We believe the phrase is self-explanatory, and do not think of better terminology for expressing the meaning.

Question.—It has been said that certain additives which, at high feeding levels, may cause bladder stones and subsequently tumors are regarded as carcinogenic under the food-additives amendment. If such substances are really unsafe under normal conditions of use, should not a warning be sounded against eating rhubarb, spinach, tomatoes, apples, and other foods which may likewise cause oxalates to deposit and may possibly induce tumors?

Answer.—The food-additives amendment is concerned with chemicals added to foods and not with chemicals naturally present in foods. Naturally occurring poisonous or deleterious substances would be

dealt with under Section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act, which reads:

> A food shall be deemed to be adulterated if it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health.

Questions.—Section 409(c)(3)(a), in the Delaney clause, provides that it turn on the fact that an additive has been *"found to induce cancer."* Does not this mean that there is scientific data that this has occurred, based on tests which are appropriate for the evaluation of the safety of food additives? What specific data exists on which supportable findings could be made that organic arsenicals would have this effect when used in animal feeds? Who made these findings and when?

Answers.—The language quoted does mean, in our opinion, that a substance must have been found to induce cancer when fed to animals or man, or tested by other appropriate means. We do not know of any data showing that the organic arsenicals cause cancer when fed. However, the fact that inorganic arsenic causes cancer when fed raises real questions as to the safety of the organic arsenicals. These questions would have to be resolved before the Food and Drug Administration could issue any approvals under the food-additives amendment for use of organic arsenical additives in food.

Question.—Did not the Food and Drug Administration advise Congress by letter that the Delaney Amendment would add no additional substantive requirements to the food-additives amendment? In the Senate committee report (Senate Report 2422) on the food-additives bill, it is stated:

> In short, we believe the bill reads and means the same with or without the inclusion of the (Delaney) clause referred to. This is also the view of the Food and Drug Administration.

Is this position correct?

Answer.—At the time referred to we had already interpreted the pesticide-chemicals amendment as barring approval of a residue on food of a pesticide that causes cancer when fed, and we advised the Congress that we would interpret the food-additives amendment in the same way even without the Delaney Amendment. Since the food-additives amendment became law, we have found that it bars approval of a chemical for use in animal feed if the chemical can produce cancer

when fed to laboratory animals, even though as used it has no adverse effect on the animal and leaves no residue in food derived from the animal. This was not foreseen. Since it is not necessary to protect the public health, Secretary Arthur S. Flemming has said he will ask Congress to remedy this particular problem.

Question.—The Food and Drug Administration has informally stated on several occasions that it is not in sympathy with the Delaney Amendment language, since it is unrealistic and unnecessary, but that as a matter of law any relief would have to be provided by Congress. Would it not be fair and appropriate for the Food and Drug Administration to advise the appropriate Congressional committees of the agency's position?

Answer.—We do not recall the statements attributed to us. Our Department will advise Congress of our position. Our position is that the principle of the Delaney Amendment is sound, and we will support it. As discussed in the answer to another question, there is a technical correction that we will recommend, but we would oppose vigorously any effort to rescind the Delaney Amendment until science develops a satisfactory method of determining what is a safe feeding level in man of a substance that produces cancer when fed to man or animals.

Colors

Question.—How do you defend the basic concept of fair government in the present campaign to delist virtually all coal-tar colors while at the same time legislation is proposed which would permit their continuance, at least provisionally, for a period of years? *Answer.*—Delisting of colors that are not "harmless" is required by present law. The proposed legislation would not require provisional listing of delisted colors. Only those that could be used legally on the day prior to enactment of the color-additives bill would be entitled to provisional listing; if coal-tar colors, they would be entitled to provisional listing only if a batch had already been certified and the color had not been delisted.

Question.—Mr. Harvey has said that the old coal-tar-color law was not workable because it was impossible to prove that toxic effects observed in exaggerated animal tests would not be experienced in the actual use of the product at low levels. How can you consider the cancer clause workable when it has the same limitation—that is, it requires proof that one particular kind of toxicity (carcinogenicity)

observed in exaggerated tests will not be experienced in the actual use of the product at low levels. This proof is impossible to obtain.

Answer.—The first part of the question does not reflect accurately Mr. Harvey's full statement about the coal-tar color sections of the law. The coal-tar color provisions are unrealistic, basically, because they are based on the premise that substances may be judged harmless without regard to the concentration employed. Scientists tell us this is not true. The cancer clause of the food-additives amendment is proper, in the present state of knowledge of cancer, because many informed scientists say they do not know what would be a safe feeding level for a substance that produces cancer when fed to laboratory animals. Under these circumstances cancer-producers should be barred from food.

Questions.—(1) On what basis was the now-proposed January 1, 1960 expiration date for certificates, covering batches of color *previously certified* by the FDA, established?

(2) What is the real purpose that the FDA is attempting to achieve by attempting to cancel the certificates on existing batches of color, which the FDA previously issued, and upon which the buyers have relied in good faith?

(3) What is the legal authority for a cancellation of certificates?

(4) If the FDA can sustain its position, why cannot the owner of an inventory of color from batches previously certified bring suit under the Federal Tort Claims Act for damages caused by the FDA's negligence in certifying them?

Answers.—(1) On the basis that users should not be allowed to use a color indefinitely after it becomes apparent that it is no longer eligible for listing.

(2) The purpose FDA is attempting to achieve is to stop the use of colors that have been found not suitable for use in food under present law.

(3) The authority to issue a certificate necessarily carries the authority to cancel it when the basis upon which it was issued is found not in accord with the law.

(4) The Federal Tort Claims Act is not applicable to this situation.

Question.—We would like to know what dyes are approved for marking meats and stamping citrus, avocados, etc. *Answer.*—Certified food colors.

Question.—Will the FDA grant blanket approval for certain inorganic pigments to be formally exempted from the clearance provisions of the amendment in addition to those listed in the December 9, 1958 issue of the *Federal Register? Answer.*—There are no plans to do this.

Experience Based on Common Use in Food

Questions.—(1) Isn't it true that the Food, Drug, and Cosmetic Act says that any system of components which has been used in and/or about food for several years without apparent adverse effect on health is considered safe and does not require specific clearance? (2) As a corollary, aren't the questions and problems discussed at this meeting concerned with materials and systems of components which are new or become questionable?

Answers.—(1) The language in the amendment is more restrictive than the language in Question (1). So the answer to this question would have to be "no." (2) Food additives are, in general, substances not generally recognized by competent experts as safe for their intended uses; the subject of the conference is, in general, food additives.

Experts

Questions.—(1) Since Section 201(s) refers to "experts qualified by scientific training and experience to evaluate its [the particular ingredient's] safety," what is the basis for insisting that some 800 experts must have known of the usage in order to meet the statutory test? (2) On the assumption that an administrative agency ought to try to honor Congressional intent, would it not be good administration to determine that the relevant population is any group of competent experts who have worked with the particular ingredient? (3) If there has been adequate testing and recognition by competent experts, has not the purpose of the statute been honored? (4) Is not any other view really an attempt to nullify the grandfather clause in Section 201(s)?

Answers.—(1) The Food and Drug Administration does not insist that any given number of experts must have known of the use of a substance for it to be recognized as safe. The present procedure is, rather, an effort to give scientists generally an opportunity to express their views about the safety of a proposed use of a substance that has not been cleared through the petition procedure set forth in the law. (2) Congressional intent, as we understand it, was to relieve a substance of the necessity of getting clearance by the petition procedure only where competent experts *generally* recognized its use as safe. Where a

small group of competent experts have tested a chemical adequately and have shown that it is safe for a proposed use, that is proper datum for consideration in a petition for a regulation sanctioning the proposed use. (3) If the recognition of safety is general, yes. If there is not general recognition of safety by appropriate experts, then the purpose of the statute would require the filing of a petition seeking a regulation to sanction use of the additive. (4) No.

Extension of Time

NOTE: Most questions on extension of time have been answered by a statement of policy (Section 121.85 of the Food Additive Regulations), published in the *Federal Register* of December 31, 1959. This tells what information FDA needs in order to consider requests for extensions. Consequently, these questions are not repeated here.

Question.—A manufacturer is seeking to have a product which was in food prior to January 1, 1958, classified as exempt under the "generally recognized as safe" provision. On the basis of data submitted, the Food and Drug Administration has not yet reached a final decision. Will the FDA honor a request by the manufacturer for an extension of the effective date of the amendment from March 5, 1960, to March 5, 1961, to enable the manufacturer and the FDA to resolve the status of the food product? *Answer.*—It depends upon the facts in the matter. It is evident that an extension could not be granted unless the evidence showed that it would involve no undue risk to the public health.

Questions.—(1) What information must be made available to the FDA in order to obtain the 12-month extension? (2) Is a history of safe usage alone sufficient?

Answers.—(1) See the *Federal Register* of December 31, 1959. (2) Not necessarily.

Question.—When, as and if an exempt list is issued, will the Administration grant an extension of time to allow petitions to be filed for those chemicals on the proposed list which are omitted from the final list? *Answer.*—Yes, unless the reason for omitting them would also be reason for concluding that the extension could not be granted without undue risk to the public health.

Question.—In connection with two major classes of materials—artificial flavor components and packaging materials—it appears that much, if not most, of the materials in use will not have clearly resolved status by March 5, 1960—or even by March, 1961. What should users do in the *meantime?*

Answer.—Submit requests for extension. (FDA has since advised that a product under consideration for extension will not be the subject of legal action under the food-additives amendment without prior notice.) The law provides that extensions may not be granted beyond March 5, 1961.

Question.—Will the Food and Drug Administration recognize the difficulties the food-packaging industry is laboring under to meet the March 6, 1960 deadline for completing all necessary extraction tests and toxicological research required to permit the filing of a petition where necessary, and grant a blanket extension of at least one year for those packaging materials in use and generally considered acceptable prior to January 1, 1958, to permit the completion of sufficient research to allow for a reasonable evaluation of the continued acceptableness of such packaging materials?

Answer.—Extensions of time will be granted on the basis of the facts supplied about uses of individual products. The Secretary of Health, Education, and Welfare would have no way of determining, as required by law, that blanket extensions would be "without undue risk to the public health."

Filing Procedure

Questions.—(1) Are toxicological data submitted with a petition confidential? (2) How can others use such data for a petition of their own?

Answers.—(1) Yes. (2) By obtaining written permission from the original petitioner.

Question.—Is it not recognized by the Food and Drug Administration that there are certain matters related to the security of new product developments where industry's judgment is perhaps more experienced than that of the FDA? If this is the case, why does the FDA continue to insist upon the disclosure of a company's name in the filing notice of a petition when some members of industry have repeatedly asked that this disclosure be at the option of the petitioner?

Answer.—While the food-additives bill was under study, Congress considered whether to require that food-additive petitions be handled on a "private" or a "public" basis and settled on the latter. Publication of the filing notice, including in it the name of the petitioner, follows the practice used for some years in publishing proposed amendments to food standards under the Hale Amendment.

Generally Recognized as Safe

Question.—Will lists, similar to the forthcoming revision of the December 9, 1958 list, be issued covering such unintentional food additives as plasticizers, defoamers and lubricants—for example, lubricants for aluminum food containers? *Answer.*—Yes.

Question.—On the "white lists," propylene glycol is listed as an emulsifier and propylene glycol monostearate is not listed. Since propylene glycol is not an emulsifier, was the monostearate what was intended to be listed? *Answer.*—If propylene glycol monostearate is manufactured from lots of "food grade" stearic acid and if the final product is also of food grade, we believe it would be generally recognized as safe (GRAS). Although propylene glycol itself is not an emulsifying agent, we understand it is sometimes used as a solvent aid in emulsifying food products and hence it was included in the white list of emulsifiers.

Questions.—Referring to a chemical substance in use with food prior to January 1, 1958, the statute directs the qualified scientific experts to rely alternately on "experience based on common use in food," in determining that the substance has been adequately shown to be safe.

(1) What constitutes "common use in food" for this purpose? Is it number of units sold, such as 10,000 or 100,000, or the time period during which the product was on the market, such as six months, or is it some combination of both?

(2) Assuming sufficient past use has been made to be "common use in food," if there has never been an ill effect recorded from the food in which the particular substance was used, is anything further required to establish the adequate showing of safety in the expert's mind, in the opinion of the Food and Drug Administration?

Answers.—(1) Common use may occur either as a result of widespread use of a product in a single food or as a result of its use commonly in a number of different foods. We have not attempted to set specific limits as the time or number of units in which a product must have been used to be in common use. (Use of a chemical in one day's production of an item that is manufactured at the rate of 100,000 units per day would hardly constitute common use).

(2) It seems likely that the qualified expert will consider more than absence of reported injuries in evaluating the safety of a chemical.

Question.—With nearness of March 5, 1960, and absence of FDA approvals of major packaging media, what are suggestions of the FDA to prevent return of the "cracker barrel" era in the processors' packaging program? *Answer.*—The Administration will publish generally-recognized-as-safe, prior-sanction and extension lists in this category.

Questions.—According to published reports, the FDA is relying heavily on the responses of about 800 experts as to the safety of substances proposed for inclusion on so-called "white lists."

(1) How were these experts selected and their qualifications determined? Are their names available to interested persons?

(2) What weight is given to the reply of an expert who indicates a lack of familiarity with a given substance and its use as a food additive?

(3) What if an expert claims to be unable to judge whether or not a given use of a substance is safe merely upon the lack of evidence of recognizable or recognized adverse effects?

(4) Toxicologists say that no final conclusions can be drawn from animal tests alone and that only reasonably safe presumptions can be made, subject to confirmation or refutation on the basis of human experience. If this is so, would not a history of apparently safe use be even more valid than the limited observations made under necessarily restricted experimental conditions?

Answers.—(1) Published lists of scientists and names suggested to FDA by its scientific personnel and those of industry.

(2) This would depend upon whether the particular expert could be expected to be familiar with the type of product involved. In any event, we are trying to find out if a substance is *generally* recognized as safe and not whether one scientist alone has an opinion. We must take into account all of the views we receive.

(3) Then he obviously does not recognize the article as safe.

(4) If this question means that a history of use should be given greater weight than the results of good pharmacological feeding studies using animals, we do not agree.

Question.—The following article contains a list of plasticizers indicated to be acceptable for use in food packaging material: "Food Packaging," by A. J. Lehman, 22 *Journal of Association of Food and Drug Officials of the United States* 159-168 (October, 1956). Are all

or any of the plasticizers included in this list still considered to be acceptable in view of the food-additives amendment? *Answer.*—Yes. We have indicated in the *Federal Register* of February 2, 1960, that they are acceptable.

Questions.—How may a potential food-additives petitioner determine whether it is a substance "generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown . . . (or through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use" and, thereby, a substance exempted by the food-additives amendment of 1958 and not requiring a petition for continued use? Will the FDA, upon request, answer this question for him? In answering such a question, will the FDA consider affidavits of such experts as the potential petitioner may have in his possession and should he submit the same to the FDA, or has the FDA established its own, not-to-be-modified criteria for this general recognition of safety? What is the FDA's current thinking on how to establish this general recognition of safety by qualified experts?

Answers.—To determine general recognition of safety, it seems necessary to have some method of letting experts generally know what substance is being considered and giving them an opportunity to comment on the proposal. This is the goal of the present FDA procedure. The FDA is not prepared to make a final decision as to the general view of scientists about the safety of newer food components without giving them this opportunity to be heard. (Of course, for such substances as salt and sugar, no polling of experts is required.) Affidavits of a few experts that they regard a substance as safe for its intended use would be a good reason for publishing a proposal that the substance be considered "generally recognized as safe," and soliciting comments of the scientific community. The FDA will consider suggested substitutes for the present method of determining general recognition of safety. The present method was described in the formal papers presented at the conference.

Question.—Enzymes have been used in foods and feeds for many years. Has the Food and Drug Administration approved, or does the Food and Drug Administration contemplate approving, the use of enzymes on the basis that they are generally recognized as safe? *Answer.*—We do not contemplate blanket approval of enzymes. If the

inquirer will let us know what enzyme and what uses of it he has in mind, we will comment further.

Question.—Mr. Goodrich has suggested that if there is any responsible minority holding a different view, the safety of an ingredient cannot be considered "generally recognized." Applying this same reasoning, is it not generally recognized by expert food and drug lawyers that the present FDA interpretation of "generally recognized as safe" renders that phrase restrictive and almost meaningless? *Answer.*—No.

Question.—Does the Food and Drug Administration have any plans to change the procedure whereby it decides if the "general recognition as safe" exemption applies to a particular substance? If so, what alternatives to the "scientific popularity poll" procedure are being considered? *Answer.*—See the answer to an earlier question.

Guarantee

Question.—Food manufacturers who use chemicals in food processing or as ingredients commonly have asked their supplier of chemicals to furnish an "FDA guarantee." The new additives law, however, places emphasis on the *use* to which the chemical is put, which is not within the control of the supplier. A Manufacturing Chemists' Association committee has tentatively recommended that the form of guarantee be changed so that the supplier would in effect now merely guarantee that what he shipped was not adulterated or misbranded, etc., thereby placing responsibility for actual use in food upon the food manufacturer. What is the reaction of the FDA and The Food Law Institute experts to the MCA's approach?

Answer.—The Food and Drug Administration's reaction is this: We agree with the MCA that a firm can legally guarantee only that which it has shipped. The article introduced into interstate commerce can be guaranteed to be neither adulterated nor misbranded. The receiver of the article guaranteed is protected if he merely passes the article on without change. We do not believe, however, that the use of this guarantee will place the responsibility for actual use in food upon the food manufacturer. Where the supplier of a substance knows, or has reason to know, that the particular shipment will be used in food production, packaging, etc., the intended use of the article makes it subject to the Federal Food, Drug, and Cosmetic Act, and

the shipper is responsible if the article is adulterated because it is a food additive for which there is no effective regulation. More specifically, the supplier of an ingredient can guarantee only the ingredient and not the ultimate food in which the ingredient is used. The supplier of the ingredient may be held legally responsible for shipping the ingredient under the Federal Food, Drug, and Cosmetic Act if it is a "food additive" and if he knows, or has reason to know, that it will be used in food, and there is no regulation permitting its safe use and no extension of the effective date has been granted.

Questions.—(1) What guarantee could we get from the supplier of our raw material used in the manufacture of adhesives?

(2) What guarantee could we get from the supplier of adhesive products which we resell or which we use?

(3) What would be the measure of protection afforded to us by these guarantees in each case?

Answers.—(1) The only guarantee one may obtain from a supplier, insofar as the Federal Food, Drug, and Cosmetic Act is concerned, is the guarantee described in Section 303(c). Basically, this guarantee is to the effect that the substance covered by it is neither adulterated nor misbranded. This would allow a food manufacturer receiving supplies to obtain a guarantee of raw materials that are intended for use which results directly or indirectly in their becoming components of foods. There is no provision in the Federal Food, Drug, and Cosmetic Act for a guarantee of raw materials for use in the manufacture of adhesives, except to the extent that the intended uses of the raw materials in adhesives may result in their becoming a component of food. This does not mean that a person who receives raw materials for use in the manufacture of adhesives should not inquire of his supplier as to the identity of the components in the adhesives, as to any likely migration from the adhesives to the food, and as to whether the substances used in the adhesives have been approved by regulation, by an extension of the effective date of the Act or by inclusion on a generally-recognized-as-safe list. Indeed, the adhesives manufacturer may very well be justified in asking his supplier to guarantee that the raw materials are in full compliance with the food-additives amendment or are exempt from the food-additives amendment. But insofar as the Federal Food, Drug, and Cosmetic Act is concerned, this guarantee has legal significance only to the extent that it covers a

food and guarantees that that food is neither adulterated nor misbranded. When the substance is used in the manufacture of adhesives known to migrate to food they are "food additives" by definition because their intended use results, or reasonably may be expected to result, in their becoming components of food. They are thus adulterated food if they have not been proved safe under the recent amendment.

(2) As to the supplier of adhesive products which you resell, you can obtain a valid guarantee following the pattern set out in our regulations under Section 303(c) of the Act, to the effect that such adhesive products are food (because of their intended use)—neither adulterated nor misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act. Such a guarantee would protect you where you simply buy adhesive products and resell them as you receive them. Where the adhesive is used by you in a packaging material and where packaged food is shipped interstate, the guarantee which you obtain from the supplier of the adhesive would have no legal validity in protecting you from prosecution because the packaged food was adulterated.

(3) We have indicated above that the protection afforded by these guarantees applies only to criminal actions under the Federal Food, Drug, and Cosmetic Act for the introduction or delivery for introduction into interstate commerce of food that is adulterated. If you have a guarantee received in good faith from a person who produced the food, and you simply pass it along in the same form in which you received it, the guarantee would provide legal protection against criminal prosecution. These guarantees may have other consequences in civil litigation and they may have an influence upon the Food and Drug Administration in its decision whether to recommend prosecution in those cases where the food became adulterated solely by the reason of the use of an unsafe additive by a person who held a guarantee on the additive to the effect that the additive was safe. However, the legal protection afforded by the food-additives amendment to persons who use substances covered by this new law is provided by the requirement that public regulations be issued specifying what substances can safely be used and how they may safely be used. All you need to do is check the regulations, in which we have listed substances in three classes—those we believe to be generally recognized as safe; those for which we have extended the effective date of the law to permit the accumulation of additional safety evidence; and those covered

by regulations providing for their safe use. If the substance is not listed, you may inquire about the existence of a prior sanction or whether the substance may be regarded as generally recognized as safe.

Question.—The FDA has by regulation suggested forms of guarantees under the Act as to misbranding or adulteration. Customers are now requesting similar assurances as to the safety of additives. A guarantee will suffice when the additive is a food but not when in another form, as in packaging materials. Will the FDA recommend or suggest an adequate statement to use in such situations, particularly warranting as to the safety of additives in packaging materials?

Answer.—The Food and Drug Administration has no plans for recommending a guarantee on the safety of additives in packaging materials. We believe that the forms of guarantee which we have recommended in our regulations go as far as a guarantor can legally go and that there is no need to provide a different guarantee which applies specifically to packaging materials. If the packaging material is a substance the intended use of which may reasonably be expected to result, directly or indirectly, in its becoming a component of food, it is a "food" by definition and it is adulterated if it is a food additive which is unsafe within the meaning of the new law.

Question.—Is it useful or advisable for manufacturers of materials which may be used for coating paper which is used for packaging to give guarantees to packaging manufacturers or their suppliers?

Answer.—The problem is not whether it is useful or advisable for the manufacturer of materials for coating paper to give food and drug guarantees. The practical question is whether you can sell the substances without providing such guarantees. Experience has shown, we believe, that a great many substances used in packaging materials simply cannot be sold unless they have Food and Drug Administration approval. As a strictly legal matter, however, the guarantee can be made applicable only to the materials shipped by the guarantor. If he sells paper, he can guarantee the paper; if he sells chemicals to be used in coating paper, he can guarantee only the chemicals; and he can guarantee the paper and the chemicals only in terms that they are food (food additives) which are neither adulterated nor misbranded. There is no provision under the law for a supplier of coating materials to provide a legally valid guarantee which would protect the person who sells food packaged in the coated paper from all violations of the

law or, indeed, from violations which result because the packaged food became adulterated as a result of migration of substances from the coating of the paper to the food.

Questions.—(1) If the producer of a chemical substance guarantees to a food processor that the substance is not a food additive within the meaning of the Federal Food, Drug, and Cosmetic Act and the processor incorporates this substance into food, is the processor immune from criminal prosecution under Section 333(c) of the Act if it is subsequently found that the chemical substance is a food additive which had not been cleared for use by the FDA? Assume that the food processor was entirely unfamiliar with the nature of the ingredients of the chemical substance and that the producer of the additive refused to inform the processor of the nature of the substance's ingredients.

(2) What is the specific offense, if any, of which the producer of the uncleared additive is guilty? Is the producer of the additive guilty of adulteration of food?

Answers.—(1) There is no provision under the Federal Food, Drug, and Cosmetic Act—more specifically, Section 303(c) of the Act —for a guarantee to the effect that a substance is not a food additive. The guarantee can apply to a food additive only by providing assurance that food is neither adulterated nor misbranded. Food is adulterated if it is, or bears or contains, a food additive for which there is no effective regulation providing for safe use or for which there has been no extension of time. Therefore, the guarantee in the form recommended in our regulations provides all the protection that legally can be provided under the law. It would not protect a food producer who used an ingredient in producing another food if the shipment of this processed food resulted in a violation of the Act. The assumption in the first part of the question is an unwarranted one because we cannot visualize a situation where a food processor would use such an ingredient.

(2) The producer of an uncleared additive is guilty of no offense. An uncleared additive is defined as an adulterated food. The interstate distribution of adulterated food is the offense. The distributor of the additive, even though he does not ship it interstate, may very well be charged with causing the introduction or delivery for introduction into interstate commerce of adulterated food or causing food to be adulterated while held for sale after shipment in interstate commerce.

Question.—To what extent may a food packer rely upon the guarantee obtained from the manufacturer of a food-container supplier, where such food container is later found to be a food additive?

Answer.—The guarantee given by a food-container supplier provides legal protection only to those who distribute the containers in exactly the form in which they received them. When food is placed in the container, the guarantee does not apply to protect the shipper of a packaged food even in the event that the adulteration results solely from the migration of an unsafe food additive from the package to the food.

Labeling

Questions.—Have any reliable studies been made to determine what kind of labeling informs consumers adequately? If not, are any planned? *Answer.*—The Food and Drug Administration has not conducted, and does not plan, general studies of the type envisioned in the question.

Questions.—For more than two decades the Administration has had a common-sense view on what was a "common or usual name." Will you please explain how the interest of the consumer is served by stringing out a list of jawbreaker chemical names on a food label (for example, Food Additive Order No. 1 for Monsanto's antioxidant, Santoquin. This order specifies that the labels must indicate the presence of 1,2-dihydro-6-ethoxy-2, 4-trimethyl-quinoline). Is the average consumer competent to understand these names? Is it not a distortion of the real objectives of the Act to require long listing of jawbreaker chemical names instead of an adequate statement of the functional purpose of an added food ingredient? If pretesting and prior approval under the food-additives amendment satisfies public safety, why the insistence upon this jawbreaker name-ingredient disclosure?

Answers.—The drug industry has made commendable strides in adopting common names for chemicals used in drugs, and the Food and Drug Administration has suggested that the food industry consider the development of a procedure for establishing simple common names for food additives. The consumer has a right to know what is in the food she buys. The law safeguards this right. Neither the letter nor the purpose of the law would be served by allowing a statement of the functional purpose served by an additive as a substitute for its common name.

Question.—If a product contains (1) "glyceryl lactostearate with mono- and diglycerides" plus (2) *additional* mono- and diglycerides do you declare

(a) Glyceryl lactostearate with mono- and diglycerides or
(b) Glyceryl lactostearate
Mono- and diglycerides, or
(c) Glyceryl lactostearate with mono- and diglycerides
Mono- and diglycerides?

Answer.—As per (a) or (b).

Lists

Questions.—Will the Food and Drug Administration issue and keep current a compilation of the substances: (1) approved for use pursuant to the petition procedure? (2) determined, in its opinion, to be generally recognized as safe, at the present state of scientific knowledge? (3) determined, in its opinion, *not* to be so recognized at this time? If not, why not?

Answers.—(1) Yes, by reprinting the orders as they are published in the *Federal Register.* (2) Yes, as lists of substances generally recognized as safe are published, they will be reprinted and mailed out according to the food-additives mailing list. (Note, however, that no attempt will be made to include on the lists such universally recognized substances as salt and sugar.) (3) No, because this would require knowledge of all the substances being considered by industry for possible use in food and knowledge of all uses of these substances being considered. The FDA does not have this knowledge. However, it will comment on specific questions about specific chemicals.

Question.—What is the status of the so-called "exempt" list of chemicals? Many users of chemicals on the proposed list appear to be expecting the list to be issued and, therefore, are doing nothing to file petitions for regulations covering the use of such chemicals as intentional or incidental additives. *Answer.*—One list was published on November 20, 1959, another on January 19, 1960, and others will follow.

Question.—Does the FDA have available or will the FDA shortly make available a list of commercial laboratories to which small businesses and industry might turn with the assurance that these laboratories are approved by the FDA as qualified for food-additives research and whose findings will be acceptable to the FDA in the qualifying of products? *Answer.*—We do not have any plans to "approve" commercial laboratories performing food-additives research. Reliable

findings developed by any responsible laboratory will be accepted by the FDA in considering food-additives petitions.

New Drugs—Veterinary

Question.—When the Food and Drug Administration permitted an application for a new drug designed for consumption by animals to become effective prior to the food-additives amendment, did the agency, in determining that the drug was "safe," take into consideration the fact that the drug was to be used for consumption by animals and might leave a residue? *Answer.*—Yes.

Questions.—Our attorneys advise us that, in the case of a substance for which, prior to the food-additives amendment, a new-drug application was submitted for use of the substance in animal feed, a reasonable legal position now would be that although new manufacturers of the substance or the feed would be required to submit new-drug applications, the approval of the original new-drug application could be held to constitute prior approval by the Food and Drug Administration of the substance as safe so that the food-additives amendment would not be applicable.

(1) Can you say that that position is legally invalid?

(2) Would not that position be a sensible one from the viewpoint of fair and orderly administration of the food-additives amendment?

Answers.—(1) No, because the matter has not been tested in the courts.

(2) The new-drug section of the law very clearly, in our opinion, is designed to provide for approval of a specific plant, under the specific controls set forth in the new-drug application, and labeled with the specific labeling provided for in the application. In the case of new drugs in animal feeds, it is apparent that the establishment of an adequate control procedure to insure incorporation of the intended amount of drug in the feed is an integral part of the safeguard afforded by the law. While we cannot state flatly that the other view is invalid, we can state our opinion that it is incorrect and that it would not contribute to fair or orderly or legal administration of the new-drug section of the law.

Question.—Since Section 201(s) reads on the *ingredient*—and either makes it a food additive or exempts it from the amendment—how do you reconcile the FDA position that an effective new drug application exempts an additive used in animal feeds only for the applicant? *Answer.*—See the answer to an earlier question.

Other Agencies

Question.—In view of the complexity of the food-additives amendment and of the administrative regulations and orders thereunder, a chaotic situation is likely to arise if uniform food-additive legislation should not be adopted by state and local agencies. What steps are being taken to avoid such a situation? *Answer.*—For a great many years, the Food and Drug Administration has encouraged states and local agencies to adopt, in the food, drug and cosmetic field, legislation which is patterned after the Federal Food, Drug, and Cosmetic Act. A number of states have adopted what is known as the "uniform" law. The Administration will encourage these states to amend their uniform laws to bring them into harmony with the pesticide and food-additives amendments and will continue to encourage others to adopt uniform legislation.

Question.—The case of a university that sold contaminated (experimental animal) beef has been cited. Is this not within the scope of the Meat Inspection Division of the Department of Agriculture, and not of the FDA?

Answer.—The Meat Inspection Division of the Department of Agriculture has control of meat in inspected establishments but the Food and Drug Administration is responsible for establishing the allowable tolerances for pesticides and food additives in meat. Also, if meat were found on the open market after shipment in interstate commerce with illegal residues of pesticides or food additives, the Food and Drug Administration would have authority to take legal action against it. Bear in mind, too, that, under the food-additives amendment, additives for use in meat or poultry may not be shipped in interstate commerce to an inspected establishment unless the FDA has published a regulation sanctioning use of the material in the product.

Packaging

Questions.—Assume a metal can, the intended use of which results in a chemical substance (first used in March, 1958) from its inner coated surface becoming a component of the food packaged in it. Assume that this chemical substance is not generally recognized as safe and has not been previously sanctioned by any governmental agency and that the cans are shipped to the food packer, who will fill them from another state.

(1) Does the Food and Drug Administration interpret the Federal Food, Drug, and Cosmetic Act, as amended, to mean that the empty cans are adulterated foods under Section 402(a)(2)(A) because they are unsafe food additives?

(2) If so, can a shipment of these empty cans be seized when it is delivered for introduction into interstate commerce under Section 301(a)?

(3) If the empty can is an adulterated food because it is an unsafe food additive, is it a food for any other purpose of the Act—that is, would the empty can be misbranded under the law because it was not labeled as foods are required to be labeled or would can-manufacturing plants be subject to inspection under Section 704?

Answers.—(1) The Food and Drug Administration does not believe that empty cans are adulterated foods.

(2) We do not contemplate the seizure of empty cans delivered for introduction into interstate commerce.

(3) If we found a food producer with a supply of cans which would result in the canned food's being adulterated because the can would contribute an unsafe food additive, we would not wait for the food to be canned, and thus adulterated, before undertaking some action to prevent this adulteration. We would probably undertake seizure of the cans at the point where the cans were being filled, and we would try to take this action before more than a few cans were actually filled so as to minimize the loss of food, all of which would become adulterated once placed in the cans. We do not believe that an empty can requires labeling as a food. We believe that can-manufacturing plants are subject to inspection to detect possible violations of the food-additives amendment.

Questions.—(1) Do packaging items such as butchers' wrap, molded meat trays, etc., which are used to transport food from the store to the home, come only under the jurisdiction of the food-additives amendment?

(2) Do molded fibrous and plastic containers and wooden containers used to transport raw fruits and vegetables come under the food-additives amendment?

(3) If a packaging item is used to package raw fruits and vegetables and an accidental contaminant is present in the item which has had a tolerance established under the Miller Amendment and if the

amount extractable by simulated solvents is calculated to be equal to, or less than, the tolerance established, is this all that is needed to satisfy the FDA?

Answers.—(1) Packaging items such as butchers' wrap, molded meat trays, etc., used solely to transport food from store to home (not in interstate commerce), do not come under the food-additives amendment. It is our recommendation, however, that any question of safety arising from migration of substances from these materials to food should be resolved, even though technically the food-additives amendment does not apply to them.

(2) This type of container used to transport fruits and vegetables would come under the food-additives amendment if its use could reasonably be expected to result directly or indirectly in contributing some component of unknown or uncertain safety to the fruits and vegetables.

(3) The Miller Amendment tolerances apply only to the approved uses of pesticide chemicals in producing and distributing raw agricultural commodities. Such a tolerance would not be applicable to the accidental contamination of the raw agricultural commodity for which a tolerance has been established. This kind of accidental contamination is strictly forbidden and would be a violation of the prohibition against added poisonous and deleterious substances that are avoidable in good manufacturing practices and are not required in production.

Question.—The following question and answer is quoted from a report of the 1958 conference:

> Question: It was stated Monday morning by Mr. Dunn that responsibility for compliance with the amendment rests directly on the supplier of food additives. The safety of a particular food component or food additive cannot legally come into question until it is "food" within the meaning of Section 402—that is, food in the form intended to reach and be consumed by the consumer. How then can a supplier of a food additive have the direct responsibility for testing for safety prior to the time that such additive actually becomes incorporated in food?
>
> Answer: If the additive is shipped for use in food, it is a food. (See Section 201(f) of the Food, Drug, and Cosmetic Act.)

Please clarify this answer further with respect to incidental additives which might arise from food packaging components. When packaging films and packaging adhesives are shipped for use in food, and one or more of the components might migrate to a food, are the packaging films and packaging adhesives "foods"? When the manu-

facturer of said components ships these components to the film or adhesive manufacturer, are these components "foods"?

Answer.—When packaging films and packaging adhesives are intended for use in food and one or more of the components may reasonably be expected to migrate to the food, the packaging films and packaging adhesives are food additives under the definition in the statute and are subject to regulations to provide for their safe use. When the manufacturer of components ships them to film or adhesive manufacturers with no reason to expect that they will be used on foods or that they will contribute materials by migration to foods, the manufacturer is not required to treat them as food additives. Even where the manufacturer has knowledge that some of his components may be used in food films or food-packaging adhesives, this alone does not make them food additives. However, where there is reason for a component manufacturer to know that a specific shipment of film or adhesive is destined for a food use and may reasonably be expected to result in a food additive, we believe the shipper has the responsibility for considering the components food additives and that their shipment in violation of the food-additives amendment would be subject to regulatory action under the new law.

Question.—Under what section of the Federal Food, Drug, and Cosmetic Act could the FDA proceed against a packaging manufacturer? Intended use may make packaging materials food additives; intended use cannot make them foods. All the violations are defined in terms of processing or shipping food in some way. In short, I'm asking for the statutory language upon which Mr. Goodrich relied in his talk on guarantees.

Answer.—The Food and Drug Administration can proceed against a packaging manufacturer when his action results in packaged food's being adulterated. This could be done on either the theory that the manufacturer caused the food to be adulterated or the theory that the packaging itself is a food additive which is unsafe within the meaning of the law. It is true that all of the violations are defined in terms of the interstate distribution of food. The cases hold that persons causing food to be adulterated may be held responsible for the interstate shipment of that food and for any act which results in food's being adulterated while held for sale after shipment in interstate commerce.

Questions.—What, in the view of the Food and Drug Administration, is the area of responsibility of (1) a raw-material producer, (2)

a package manufacturer and (3) a package user in respect to the problem of the migration of packaging materials? Specifically (if possible), what is the impact of the Act upon the manufacturer of an adhesive used in manufacturing packages where the adhesive is, or may be, used with various kinds of packaging materials which, in turn, are, or may be, used to package various kinds of food?

Answers.—The Food and Drug Administration believes that the raw-material producer, the packaging manufacturer and the packaging user all share the responsibility for safety clearance of packaging materials which migrate to food. The ultimate responsibility for obtaining a safety regulation, of course, rests upon a person who brings the food additive into the food supply. Literally, of course, this is the package user, but we feel that both the supplier of the raw material and the person who made the package can be held responsible for the adulteration caused by them in offering unsafe raw materials for packaging for food use.

Specifically, the manufacturer of an adhesive used in packages can be held responsible under the Federal Food, Drug, and Cosmetic Act if he knows, or has reason to know, that a specific shipment of the adhesive by him is intended for use in food packaging and if he has facts on which it may reasonably be expected that the adhesive, directly or indirectly, may become a component of the food. Where the adhesive is generally recognized as safe, of course, the food-additives amendment would not apply, and this is true also where the adhesive has a prior sanction. But the distribution of an adhesive of an unknown or uncertain toxicity for use in food packaging would give rise to regulatory action against packaged food to which the adhesive had migrated; this may be followed by action against the persons responsible for the use of the food additive without the necessary proof of safety.

Questions.—Are there any transparent materials other than polyethylene suitable for packaging fatty foods? What packaging materials (flexible) are suitable for packaging fatty foods—even if not transparent? *Answer.*—A number of transparent packaging materials suitable for wrapping fatty foods are acceptable and are covered by prior sanctions. Additionally, there are many nontransparent packaging materials that are entirely suitable, since they do not contribute questionable substances to the packaged foods. The FDA will be

glad to comment on specific materials when furnished data about them and their uses.

Question.—If waxes as such are cleared for use in food packaging, to what extent may a purchaser of waxes rely on this clearance to obtain clearance for packaging materials manufactured from the wax? *Answer.*—No clearance would be necessary where the wax for this intended use meets the specifications of the regulation and is employed in conformity with the conditions of use recognized by the regulation.

Questions.—Commissioner Larrick has indicated that any doubts about the use of polyethylene in food packaging are limited to "fatty foods." Will you define what distinguishes a "fatty" food from a "nonfatty" food in this context? Second, where a "fatty" food such as a corn chip or potato chip is packaged in a polyethylene bag or polycoated bag, but the area of contact between the food and the bag is very limited because of the nature of the food, does the Food and Drug Administration object to use of polyethylene? Is there any polyethylene suitable, at present, for packaging "fatty" food? What are the prospects for such polyethylene in the near future? Polyethylene wraps are not allowed for high-fat foods but are allowed for low-fat foods. Is there a definite percentage of fat in the food that is the division line between high-fat and low-fat foods? If the answer is "no," what is the proper criterion? Does the FDA presently favor any special type or characteristic (for example, high v. low molecular weight, high v. low density, etc.) of polyethylene in the packaging of "fatty" foods?

Answers.—The suitability of polyethylene for use in packaging of so-called "fatty foods" is under intensive investigation by industry. Evidence presented to the FDA justified a year's extension of the effective date of the food-additives amendment with respect to polyethylene for fatty foods; this added time is expected to permit the status of the packaging material to be resolved completely.

We have not attempted to arrive at any specific percentage figure as a dividing line between high-fat and low-fat foods for packaging purposes; considerations in addition to the fat content must be taken into account in evaluating the suitability of a wrapping material. The FDA is glad to offer an opinion on the status of any particular food upon request.

The experiments on polyethylene with which we are acquainted do not indicate at this time that the molecular weight or density of this

packaging material is the complete answer to its acceptability. The important point is to be sure that any polyethylene accepted for use in wrapping food be so manufactured that substances which migrate from it will migrate only in safe quantities.

Question.—Should we be concerned only about dry adhesive film or do we consider the entrapment of volatile ingredients as a problem? *Answer.*—If there is any reason to believe that volatile components of an adhesive film may affect food placed in containers made with the film, the producer should be concerned about the volatile ingredients.

Question.—Manufacturers of coated paper and paperboard often use enzymes in connection with starch coatings. The enzymes are completely inactivated by the temperatures of further processing of the paper or paperboard. With this assurance of fact, does the producer of the enzymes or the paperboard producer need to secure any clearance for the use of such enzymes in paperboard which may come in contact with food in finished packages? *Answer.*—It is necessary to have more facts in order to answer this question. If the inquirer will supply complete information we will be glad to comment.

Question.—A packaging manufacturer has data which he believes establishes the facts that if all of a particular ingredient of his material migrates into the food, the migration will be less than one part per million and that this proportion is of no toxicological significance whatever and that the amendment does not apply. Assume that Mr. Ramsey agrees on the extent of the migration and Dr. Lehman agrees it is completely insignificant. A food manufacturer demands proof that the FDA agrees that the amendment does not apply. What can the packaging man do?

Answer.—If the manufacturer believes that appropriately qualified experts generally recognize the proposed use of the ingredient as safe, he can request the FDA to include it in a list of substances proposed to be recognized as safe. Otherwise he may file a petition requesting a regulation stating safe conditions for use of the ingredient.

Question.—A packaging manufacturer has data which he believes establishes the fact that his material does not become a component of the food and that the amendment does not apply. A food manufacturer demands proof that FDA agrees. What can the packaging man do? *Answer.*—Submit the data to the FDA to determine whether the Administration agrees that his ingredient is not a food additive under

the proposed conditions of use. If the FDA agrees, the firm can so advise the food manufacturer.

Question.—What is the present situation under the food-additives amendment regarding paraffin used to make waxed paper for bread wrappers, paper milk bottles, and other food products? *Answer.*—This was discussed in the formal papers.

Questions.—What is the present situation under the food-additives amendment regarding glue used for gluing together containers for crackers, cookies, dried fruits, cereals, candy, and other food products? What is the present situation, under the food-additives amendment, regarding paperboard used for making packages for crackers, cookies, dried fruits, cereals, candy, and other food products? What is the present situation under the food-additives amendment regarding printing inks used for printing labels and containers for food products? *Answer.*—See the paper on incidental additives, presented on the first day, for a discussion of problems such as these.

Question.—Will the FDA publish a list of materials which will be acceptable for use in the manufacture of packaging materials, particularly in the paper and paperboard industry, and when? *Answer.*—Preparation of such a list has been delayed by the slowness with which the industry brought in data about the materials it uses. The paper on incidental additives should answer some of the questions. Additionally, the FDA hopes to publish, in the near future, a tentative list of substances generally recognized as safe.

Question.—Materials used in the manufacture of food wrappings but not incorporated therein, such as lubricating, cooling or tempering agents, usually are not—but conceivably can be—left on the surface of the wrappings. To what extent must it be shown that the agent is harmless under these conditions of highly unlikely contamination? *Answer.*—If it can reasonably be expected that the agents may become a part of food they should be considered under the food-additives amendment. If the decision then is that they are food additives, they should be cleared by the procedures set forth in the amendment.

Question.—Will a very long history of safe usage of known toxic materials, such as mercurials, defoamants, etc., in the manufacture of paper and paperboard, which would be present only in very low concentrations as accidental contaminants, be sufficient to continue the use of the material? *Answer.*—No. With respect to mercurials, for example, even before enactment of the food-additives amendment, the

FDA questioned the wisdom of some uses being made of them in the manufacture of paper and paperboard for use in food packaging. When a substance such as a mercurial is deliberately added in manufacturing, its presence in the finished product can hardly be considered "accidental."

Question.—If the total amount of a packaging component in a given package is below the proposed upper limit of safety for the component, is it necessary to make migration studies in order to have the Administration act on a petition for a regulation? If so, why?

Answer.—A tolerance is established at the level reasonably required to accomplish the intended physical or other technical effect (provided this is a safe level). To allow the first firm that applied for a tolerance to use up the entire quantity that might safely be employed would deprive others of their right to use the same chemical. Note also that the upper limit of safety proposed by the petitioner is not necessarily the level that the FDA can agree is safe. In general, therefore, the FDA will need to know how much of an additive gets into food before establishing a tolerance for it.

Question.—Manufacturers of various metal, paper, and flexible food-packaging materials believe that certain of their products are not "food additives" either because no substance transfers to the food, or because a substance which does transfer is generally recognized as safe. It may be that the Food and Drug Administration disagrees as to some of these products, on one or both points. Where the manufacturers are not aware that the government does disagree with their judgment as to a particular product, will the Food and Drug Administration let them know of the contrary opinion before a seizure action is begun?

Answer.—The FDA cannot agree to withhold legal actions until it has canvassed manufacturers to determine their views. The Administration is making earnest efforts to acquaint manufacturers with their responsibilities under the amendment. This conference is one example. But where a firm ships interstate a food that is in violation of the law, the FDA must hold itself in readiness to bring prompt legal action.

Question.—Ninety-nine per cent of all adhesives used in packaging do not come in direct contact with foods in the package, being sandwiched between various filmed substrates. Because of the varied uses of adhesives, simple migration tests could be extremely difficult.

What is the problem in this area? *Answer.*—It should be possible to determine readily whether migration occurs from the adhesive to the food. We share the inquirer's evident view that in most cases proper experimental work will show no problem. We do recommend that the facts be established by experiment.

Question.—The question which I am going to ask may have been answered at previous meetings held by the Food and Drug Administration. This question pertains to an incidental, rather than an intentional, additive. Wax has been used in direct contact with food in home canning practice for at least 75 years to my own personal knowledge. It has been used increasingly for the past 50 years in the packaging of food. Countless millions of people in the United States and other countries have eaten millions of tons of foods that have been in contact with waxes of various kinds for times ranging from a few days to a few years. So far no one has proved that any cancer or other toxic condition in man has resulted from eating food which has been in contact with wax. My question, then, to the Commissioner is: How can you legally prevent the use of this material when under United States law, a person is considered innocent until proved guilty.

This was written before hearing some of the speeches at this conference. Perhaps wax in food—due to its use in packaging—falls into the category of additives present in amounts too small to measure by present analytical methods, as discussed by Dr. Hall, and so the question may no longer be pertinent. Please comment.

Answer.—The wax situation was discussed in one of the formal papers. In response to the other part of the question, if a substance is a food additive, that is, is not generally recognized as safe for its intended use, then it is a violation of the law to use it in connection with food until a regulation is established sanctioning its use. To support legal action, of course, the government would have to prove that the substance was an additive and was used in a manner not provided for by the law and regulations.

Questions.—(1) What flexible packaging materials will be acceptable under the food-additives law by March, 1960?

(2) What flexible packaging materials will be prescribed under the food-additives amendment by March, 1960?

(3) What will the status of flexible packaging materials not listed under (1) and (2) be under the law by March, 1960?

Answer.—It is not possible to forecast the decisions that will be made on data not yet available.

Petitions

Question.—We have been told informally by FDA people that they look upon an order authorizing the use of a food additive as a "specification" for that material, where anyone who produces a substance that meets the "specification" for the material in the order may use his substance in accordance with the order. If this information is accurate:

(1) Is not the FDA inconsistent in its administration of the law by requiring that a petitioner submit processing information in addition to "specifications" for the substance as part of his petition and not requiring *any information*, processing or otherwise, from those individuals who enjoy the privileges of the order but do not bear the expense and effort associated with the petition?

(2) Would it not be in the interest of public safety to require that complex substances, in particular, produced by individuals other than the petitioner, be submitted to the Food and Drug Administration for approval before they are used in accordance with the order?

Answer.—(1) The purpose of a food-additive regulation allowing use of an additive is to establish the conditions under which the material may safely be used in food. This may require, among other things, (a) specifications as to purity of the additive and (b) an analytical procedure that can be used to determine that the additive is of specified purity and that it has been used within any tolerance limitation specified. In order to enjoy the privileges of the regulation, all users must observe its requirements. They apply whether the user is the individual who submitted the petition or not. It is evident, then, that the rule applies to all—not just to the petitioner. Congress considered suggestions, when the amendment was before it, that the permission for use of an additive be granted privately so others would not be in a position to benefit from the petitioner's work in developing evidence to support a regulation. It concluded that the approval of food additives should be a public matter.

(2) This question can be stated in different words such as: "Should individual batches of additives be submitted to the Food and Drug Administration for testing and certification as to purity before they may be used?" We believe it is possible to be specific enough in regulations authorizing use of additives to make batch certification unnecessary.

Question.—Is it not recognized by the Food and Drug Administration that there are certain matters related to the security of new-product developments where industry's judgment is perhaps more experienced than that of the FDA? If this is the case, why does the Food and Drug Administration continue to insist upon the disclosure of a company's name in the filing notice of a petition when some members of industry have repeatedly asked that this disclosure be at the option of the petitioner?

Answer.—When the amendment was under consideration by Congress, some proposed that the approval of food additive uses be a nonpublic transaction between the petitioner and the government. Congress rejected this approach. We believe that the name of the person who requests approval of a food additive use is information the public is entitled to under the law as enacted.

Prior Sanction

Questions.—Assume that a scientific paper published by Dr. Lehman prior to September, 1958, describes the use of a migratory packaging ingredient as "acceptable" or "approved." Assume also that FDA has published a list of such ingredients which it believes are generally recognized as safe and that this ingredient was omitted from the list.

(1) Is the published paper a sanction or approval?

(2) Does the amendment apply to the use of the ingredient referred to in the paper?

Answers.—(1) Yes—for the specific usage listed.

(2) No—for the specific usage listed.

In each case, however, it is necessary to be sure that the product in question is identical with that for which the sanction was granted. For example, a film bearing the name of a resin designated in the 1958 listing could not be covered by prior sanction if it contained other ingredients not named in the list or if the specifications for the resin were different from those of the resin granted prior sanction.

Question.—Will the government issue a compilation of the exact sanctions and approvals, qualified and unqualified, given by the various agencies enforcing the laws named in Section 201(s)(3) of the Act prior to September 6, 1958? If not, what are the reasons why this will not be done? *Answer.*—No. It will do so in special cases where warranted, but generally speaking it will not be practicable to do so.

Aside from the vast job of culling the files for prior sanctions, some of these sanctions were based on data entitled to confidentiality as trade secrets.

Questions.—In 1957, in response to an inquiry accompanied by data, the FDA advised an individual company that it regarded the use of a particular ingredient in a specific food product at a specified level as safe.

(1) Does this constitute a prior sanction or approval under the Act for that *ingredient* at that level in the particular food or a prior approval only for the company to which the 1957 letter was sent?

(2) If another user gets to see this letter, may he rely upon it as "prior approval"?

Answers.—(1) It is prior sanction for that ingredient at that level in the particular food.

(2) Yes; even without seeing the letter, he may ask the FDA if a prior sanction exists.

Regulations

Question.—Legislators have always agreed that the food-additives amendment should not discourage nor restrict new technological developments in the food industry. In light of this often-expressed attitude, has the Food and Drug Administration acted within the intent of the law by promulgating the regulation as it is now worded, applying to the exemption of substances for investigational use? This regulation, as written, completely ignores the very real and pressing situation that exists among food processors who must assess the advantages of a substance, often by organoleptic methods, before committing the substance to broad-scale technological testing and other costly studies required for a petition.

Answer.—The basic purpose of the amendment is to prohibit the commercial use of an additive not generally recognized as safe until such time as it has been tested adequately to establish its safety and a regulation has been published stating the conditions under which it may safely be used. This basic purpose would be ignored if the Food and Drug Administration were to allow commercial marketing of foods containing additives that have not been shown safe for their intended use. The law does not forbid the conduct of research studies on acceptability of an additive in noncommercial (laboratory) tests.

Question.—Many chemical compounds have been approved for use under the food-additives amendment of 1958, the Federal Meat Inspec-

tion Act and the Poultry Products Inspection Act. However, no specifications with respect to (1) the purity, (2) the quality, (3) the source or (4) the method of production or processing of any of these chemicals have been published. Does the Food and Drug Administration contemplate the issuance of any regulations relating to the purity, quality, source, or method of production or processing of any of these approved chemicals?

Answer.—At present the need for detailed government specifications of the type mentioned is not apparent. If a need should develop, of course, appropriate specifications would be issued. (In this connection, note that the products must be of a quality recognized as suitable for food use.)

Specific Chemicals

Questions.—Sodium hydroxide and potassium hydroxide are included under the heading "Buffers and Neutralizing Agents" in the list of "Substances that are generally recognized as safe" (Subpart B—Exemption of Certain Food Additives From the Requirement of Tolerances) published in the December 9, 1958 issue of the *Federal Register*. The addition of these two neutralizing agents to foods which contain vegetable oils or fats results in the formation of such compounds as potassium oleate and potassium linoleate in the food product. Can we assume, therefore, that the presence in a food product of the sodium and potassium salts of the fatty acids present in edible fats and oils is acceptable? If so, would acceptable food additives, such as mono- and diglycerides containing such salts be exempt from further testing under the provisions of the food-additives amendment?

Answer.—Use of a sodium or potassium hydroxide to break a fat down into glycerine and a soap is not a neutralizing or buffering use. Such use is not contemplated in the list referred to. The use of sodium or potassium salts of fatty acids in food would need to be considered as a separate matter. The FDA will need further details to comment on specific uses.

Question.—I would like to hear discussion on the status of divider oil (mineral oil) as it is used (1) in the divider, (2) for pan grease and (3) for trough grease.

Answer.—When mineral oil is used for those purposes, inevitably some of it enters the diet. Substances resembling it—namely, low-molecular-weight aliphatic hydrocarbon polymers, are also contributed to foods from polypropylene, paraffin waxes, microcrystalline waxes,

and petrolatum which are used in packaging materials and for other applications. We need to know the total amounts of mineral oil and related substances which enter the diet from all of these sources if we are to establish the safe usage of them. Efforts are being made to acquire these data. We will be glad to receive from interested persons reports on accurate, carefully designed experiments on this subject.

Question.—Mineral asphalt is used as a moisture barrier in multiwall paper bags, cartons, and other food containers. Under some conditions of use, there may be some migration of asphalt. Would this be objectionable? *Answer.*—Yes.

Questions.—Have any enzymes of bacterial origin been approved by the FDA for food use? If so, under what conditions have such approvals been made? What are the procedures for obtaining such approvals?

Answer.—We believe that the following microbial enzyme preparations, when produced in accord with good manufacturing practices and from strains shown to be nonpathogenic for man and animals, would be generally recognized as safe:

Derived from *Aspergillus Niger* group—
- Carbohydrase
- Cellulase
- Glucose-oxidase-catalase
- Pectinase
- Lipase

Derived from *Bacillus Subtilis* strain—
- Carbohydrase
- Protease

Derived from *Aspergillus Flavus Oryzae* group—
- Carbohydrase
- Protease

These enzymes will be included in a forthcoming list of substances proposed for general recognition of safety.

Question.—Product A is a food additive whose use in Product X is approved. Product B, which contains Product A, may also be used in Product X. Other ingredients in Product B are approved as food additives. Must approval be obtained for the use of Product A in Product B or does the approval of the use of Product A in Product X make such approval unnecessary where the sale of Product B is for

use in Product X? The foregoing assumes that the total amount of Product B is within the total amount approved for use in Product X.

Answer.—It would be helpful if the inquirer would let us know the specific products he has in mind and the conditions under which they are to be employed. This will permit us to give a responsive answer.

Question.—If each ingredient of an adhesive formula has been approved by the FDA, does it follow that the adhesive final formulation would be considered nontoxic? *Answer.*—Yes, if the ingredients were approved for use in manufacture of adhesives.

Question.—Report 2284, dated July 28, 1958, Eighty-fifth Congress, Second Session, of the Committee on Interstate and Foreign Commerce, favorably reporting the food-additives amendment to accompany H. R. 13254, states:

> On the other hand, substances which may accidentally get into a food, as for example, . . . cleaning solutions used in food processing plants, are not covered by the legislation. The additives are generally referred to as "accidental additives," since these substances if properly used may not reasonably be expected to become a component of a food or otherwise to affect the characteristics of a food.

Are the following products "cleaning solutions" not covered by the food-additives amendment: cleaning compositions and sanitizers that form water soluble solutions used to clean or treat surfaces, such as food-handling equipment and containers that come in contact with food? Such equipment and container surfaces are rinsed with fresh water after the cleaning or treatment and before food or drink comes in contact with them. The general broad compositions of these products have been in use for many years with no known harmful effects.

Answer.—If the inquirer will give specific information about the cleaning solutions he has in mind, we will attempt to answer the question. It is impossible to give a responsive answer without specific data.

Testing and Evaluation

Question.—What part will toxicity data have on the sensitivity requirements of an analytical procedure—that is, has some tentative schedule been set up, such as (1) acute oral—LD_{50}-<100 mg./kilo—0.01 p. p. m. or less sensitivity; (2) acute oral—LD_{50}-100 mg.—1000 mg./kilo 0.01 p. p. m. to 0.1 p. p. m. sensitivity; (3) acute oral—LD_{50}->1000 mg/kilo 0.1 to 1.0 p. p. m. sensitivity?

Answer.—The more toxic the additive the more sensitive a method will be needed to determine its residues. The acute oral toxicity is not the sole guide to sensitivity needed. For example, a carcinogenic agent with low acute toxicity would not be allowed in food at the 0.1 to 1.0 p. p. m. range simply because of the low acute toxicity.

Question.—If a very sensitive analytical procedure is developed by a petitioner in obtaining a regulation, will this test be available to users of the product and also to nonusers or competitors in the industry, for use on same or similar products? *Answer.*—The analytical method used to enforce a tolerance will be available to users of the additive.

Question.—Are criteria of acceptable human consumption being established so that animal-to-human ratios may be used, that is, type of animals, time, and ratios of animal dosage showing no effect? *Answer.*—Yes, acceptable methods of testing chemicals for chronic toxicity are available. Also, general guides are available for evaluating animal test data and translating the results of animal experiments to safe levels of human consumption. In the final analysis, of course, the safety evaluation must rest upon the sound judgment of experienced scientists.

Questions.—Assuming that there is some leachable compound in a pigment, what limitations are recommended in the literature search of publications? Is it acceptable to search only United States literature? How many years back should the search go? *Answer.*—Since the search of the literature is intended to develop information that will help the user of the leachable compound establish that it is generally recognized as safe or, failing that, will help him plan and perhaps shorten the experimental work needed to establish safety of the compound, we have not recommended limitations.

Question.—Will the FDA accept a negative report following a literature search as evidence of a compound's harmless nature? *Answer.*—No.

Question.—The procedure recommended by the FDA for chronic-toxicity studies in animals requires daily feeding, for two years, of diets containing high-dose levels of the test material. In applying the findings to practical use conditions, what consideration is given to the fact that some food additives may be used in foods which are eaten only sporadically or in relatively small proportions to the diet as a whole?

Answer.—In evaluating animal test data to determine whether a requested tolerance should be granted, FDA scientists consider among other things the proposed level of use of the additive in the diet, safety factors adequate for translating animal experimental data to man, the probable consumption of the food to be treated with the additive, and the presence of chemically or pharmacologically related substances in the diet. It is evident that safety considerations would, in general, require much less of a given additive in a substance such as bread, which makes up a large part of the diet, than in a food such as caviar.

Questions.—In seeking to develop a program of testing designed to establish the safety of a food additive for which program a food-additive manufacturer might then determine cost estimates in advance of starting the program, is it now possible for the FDA (when in possession of conditions of use and complete analysis of the food additive) to state positively and to define in advance the limits of a satisfactory and sufficient testing program or is the FDA so uncertain in most cases of what types of testing might ultimately be required to establish safety that it cannot guarantee that satisfactory completion of Program A (with results that look favorable to FDA) will not require the commencement of Program B and, thereafter, Program C, ad infinitum? Is it possible for a manufacturer of a food additive to commit X dollars sufficient to establish its safety by an FDA-outlined test program and to receive in advance FDA assurance that he will not ultimately have to commit 2X or 5X dollars in additional testing? (Assume that the test results bought with X dollars are judged favorable by the FDA.)

Answer.—The steps needed to conduct a sound chronic-toxicity test are well established among pharmacologists. It should be possible for an experienced testing laboratory to give a reasonably accurate statement of the cost of such a test. Of course, this does not guarantee FDA approval of the compound at the end of the test. The results may show that the tested material is definitely not suitable for use in food as proposed or they may show that there is still some real question as to the material's safety (suspicion of cancer production, for example) that can only be resolved by additional studies.

Questions.—For some years Wesson Oil has been proposed by the FDA as a food-stimulating solvent for the measurement of extrac-

tion. With the current concern for very low concentrations of extractables—as from packaging materials—and for reliable characterization of them, it is becoming evident that Wesson Oil is not a pure enough compound to permit sound analysis. In specific cases, "equivalent" solvents, capable of high degrees of purification, are being used as alternates to Wesson Oil. Does the FDA plan to standardize or generalize on the use of such alternates? Originally, a liquid food fat such as a lard oil or a vegetable oil was suggested as a simulated food solvent for extractability studies. Have any other solvents been accepted in lieu of the above for studies of "fat" extractables? We have heard that hexane used at room temperature is an acceptable test solvent. Is this correct? We have also heard that hexane is acceptable in lieu of an oil provided that a comparable extraction study is performed with ethyl acetate as a solvent. Is this correct?

Answers.—In some cases it has been possible to use separate extractions with N-hexane and ethyl acetate in lieu of extractions with lard oil or vegetable oil. It is necessary, of course, to know the substance being studied and the general nature of the problem in order to give a more specific answer.

Questions.—Has the FDA's suggested procedure for determining migration of any chemical from packaging materials in simulated food solvents changed? What is the procedure to be followed with milk and cream? What is the procedure to be followed with dry foods?

Answers.—The general procedure that has been suggested for determining migration is still applicable. In testing migration into milk, it is desirable, if at all possible, to use milk as the solvent; liquid food fat generally can be substituted for cream in making the extraction studies. In testing dry fatty foods such as the pie mixes, data should be obtained reflecting migration into fat, too. In case of dry nonfatty foods, sufficient studies could be made to show whether abrasion is likely to result in incorporation of an additive from the packaging material. If it is, appropriate tests are needed to show how much additive will be incorporated in this manner.

Questions.—(1) Is Dr. Lehman's leachability procedure of individual pigments valid for testing inorganic colorants? (2) Does the FDA contemplate modified or alternate testing procedures?

Answers.—(1) Not necessarily, because the procedure was designed for uncertifiable coal-tar colors. (2) We suggest that the procedures

outlined in Mr. Lessel L. Ramsey's paper on food-packaging materials be employed. This paper was presented at a meeting of the Safety Packaging Materials Committee of the Food Packaging Institute, at New York City, on March 3, 1959, entitled "Chemical Data Required for Evaluation of Food Packaging Materials Under the Food Additives Amendment."

Question.—The food-additives amendment involves adhesive applications primarily by possible migration of the adhesive into the food product. Would a research program, conducted either by an outside research organization or by the manufacturer of the adhesive, on adhesive migration into food categories such as fat, water, weak acid solution, etc., be acceptable as compliance with the FDA amendment? It would be understood that if a certain adhesive showed migration into food products containing fat we would not sell that adhesive for that purpose. On the other hand, it might be suitable for all other categories. It is believed that this testing procedure should be checked on the pure film of the adhesive and not on each customer's individual packaging material.

Answer.—The FDA accepts research data obtained by reliable laboratories whether independent or part of a packaging or adhesive manufacturing establishment. While tests of a pure film of the adhesive ordinarily would not be required, such a vigorous test of the adhesive would, if it showed lack of migration, give additional assurance that the material is suitable for use in packaging.

Question.—Many chemical compounds—for example, riboflavin—have already been approved by the Food and Drug Administration for use in foods. Will any testing be required to establish the safety for use in foods of mineral salts produced from such approved components? *Answer.*—We need to know the specific chemicals and uses in order to be responsive.

Miscellaneous Questions

Questions.—(1) I should like to ask: Who decides when an additive is to be used in a food and why is it to be used?

(2) Is it because some chemist has discovered a new formula which really adds nutriment to the food—or perhaps because it will make food retain its fresh appearance or its color?

(3) Is it because some producer thinks it will make the food more attractive and appealing to the consumer?

(4) We are aware that certain chemicals are preservatives, but many consumers are asking: "Are the additives being used to deceive the public into believing they are getting, for instance, riper fruit, as in the case of coloring used on oranges?"

Answers.—(1) Under the new law, after industry decides that it would like to employ an additive and why, it must supply the Food and Drug Administration with data to establish the safety of the proposed use and to show that such use will not promote deception or other violation of the Food, Drug, and Cosmetic Act.

(2)-(3) Additives may be used to add nutriment to the food or to make it retain its fresh appearance or color or for a variety of other purposes. These are legal, provided the use is shown to be safe and not to result in deception or other violation of the law.

(4) The amendment prohibits approval of an additive for uses that would deceive the consumer.

Question.—If a food component on the exempt list is also listed and defined in the *United States Pharmacopoeia* (such as glycerin), would this U. S. P. grade also be the acceptable food grade of the component? *Answer.*—Since the *United States Pharmacopoeia* is a drug compendium and speficiations for U. S. P. chemicals are not drawn up for the purpose of regulating purity of foods, the U. S. P. standards would not necessarily be specifications for food-grade products. In many cases the U. S. P. product would be satisfactory for food use.

Question.—Does the sanction of an additive for a given use—for example, mono- and diglycerides as emulsifiers—permit the use of this additive for another use—for example, as a defoamer—providing the second use is at an equal or lower level than the sanctioned use? *Answer.*—Not necessarily.

Question.—Will approval by the FDA of the manufacture and use of a food additive by Manufacturer X permit other manufacturers to produce in the same way, and use in the same manner, the same or similar additives without first applying to the FDA, even on an informal basis, for specific approval of the manufacture and use of such additive in the same manner by the other manufacturer or manufacturers? *Answer.*—Yes, as applied to the same additive; no, as applied to the *similar* additive.

Question.—What is the distinction recognized by the FDA between required or optional ingredients and noningredient components

such as migratory additives under the food standards? *Answer.*—Insofar as the food-additives amendment is concerned, there is no distinction between the two types of components. The question is not "how does the additive get into food?" but, rather, "how much gets in and is this quantity safe?"

Question.—Is a chemical which is not chemically identifiable as such after processing into a food or food packaging, because it is consumed or changed in such processing, ever subject to the Act as a food additive or a component? *Answer.*—Yes. A toxic material that is added to food and is changed in processing into another toxic material would still be subject to the food-additives amendment, and there are other situations in which substances not identifiable in their original form would be subject to the amendment—for example, food intentionally treated with radioactivity is subject to the amendment, whether or not the resulting food is radioactive.

Question.—It is expected that the FDA will approve the use of a certain emulsifying agent in certain foods at a level of 0.1 to 0.4 per cent (equivalent to 1,000 to 4,000 p. p. m.). Such approval would be based on toxicological data showing that the emulsifier is safe at those levels and on analytical techniques suitably sensitive at those levels. The FDA indicates, however, that the substances will not be on a GRAS list. Formal petition procedure for some other food uses for this emulisfier is impossible because the analytical techniques are not sufficiently sensitive to detect so little as would be used in these instances, namely two to four p. p. m. Without a GRAS status for the emulsifier, how can a person obtain FDA approval to use it in foods at the level of two to four p. p. m. or at other minute levels below the sensitivity of the analytical technique?

Answer.—We need more details in order to answer this question. If the inquirer will write giving full facts, we will be glad to comment.

Question.—Does an additive become a *component* after the additive has been approved by the FDA for intended use? *Answer.*—We do not understand the question.

Question.—What is known regarding chemicals which have known tolerance limits of themselves when ingested directly, when these same chemicals might be used in fertilizers and picked up by the plant which in turn might be used for human or animal feed? What would the FDA attitude be regarding this fertilizer use? *Answer.*—We assume that this question refers to pesticide chemicals on raw agricul-

tural commodities. Residues of these are subject to the pesticide-chemicals amendment regardless of the method by which they are applied to the growing crop.

Question.—Would you object to about 100 p. p. m. of mineral oil in grain concentrates for feeding farm animals? *Answer.*—This use would require clearance. There are tolerances for mineral-oil residues on certain grains, resulting from its use to control storage insects; mineral oil in grain concentrates resulting from legal pesticide residues on the grain used in manufacturing them would be acceptable. Mineral oil from other sources would need clearance under the food-additives amendment.

Questions.—A vast number of rubber products are used by the food industry which have direct, though short-duration, contact with food. Milking-machine inflations, milk hose and tubing, conveyor belting, gloves, gaskets, pump impellers, and molded rubber components of food processing are a few of the rubber products in this category.

(1) The belief is held by some members of the rubber industry that rubber compounds which were in use in food service prior to January 1, 1958, automatically qualify as "safe" under the "experience based on common use" provision of the amendment. Is this belief correct?

(2) Contrary to (1), other members of the rubber industry have been given to understand that every rubber compound of the several thousand involved must be proved "safe" by a qualified expert before an approval for use in food service is issued by the FDA. Furthermore, it is also understood that prior use will not be accepted as proof of safeness by the FDA. Are these interpretations correct?

(3) If the interpretations stated in (2) are substantially correct statements of the present requirements, is there any alternative which would not entail thousands of individual investigations and would still conform with the spirit and intent of the food-additives law?

Answers.—(1) No.

(2) Not entirely. Each case must be considered on its own merits from the standpoint of reasonable expectation of migration of components to food, and then on consideration of these migrants.

(3) First, evaluate the individual product and its use; there may well be no food-additives problem involved.

Question.—Would the Food and Drug Administration please explain its recent decision to deny the use of citric acid as an optional

ingredient in the standards of identity for canned tomatoes, on the ground that it will not promote honesty and fair dealing in the interest of the consumer. To all individuals not directly concerned with the situation, it would appear that the decision was prompted by interests which oppose such action for economic reasons. If there is any truth to such reasoning, is it any wonder that many food processors who cherish free enterprise and the privilege to exercise unrestricted technology in product development should be resentful of standards in general and oppose any efforts by the FDA to involuntarily standardize foods of their interest?

Answer.—In this instance, the procedures of the Hale Amendment provided for publishing the proposal and inviting comments. Many adverse comments were filed, and the entire record was reviewed in the FDA. Before making any decision, the FDA conducted further field investigations, but was not able to conclude that the proposal, if granted, would promote honesty and fair dealing in the interest of the consumer. When the proposal was denied, the proponents could have requested a public hearing on the issues. They elected not to do so.

Question.—What is the position of the FDA on specification requirements—both military and federal—that conflict with FDA regulations, especially those with formulations that do not comply with food-additives law or standards of identity or labeling requirements? There is usually a catch-all phrase that it must comply with the FDA —however, to do so would be a contract violation. Does FDA review and comment on food and container specifications pass other government agencies?

Answer.—In time of war or national emergency, we have not objected to the production of materials for use by the military which deviate from labeling or food standards requirements imposed on civilian goods (production of a specially hardened butter for use in the tropics, for example). In each case there is a clear understanding that the product is needed to further the national defense and that it will not be released for sale in civilian channels in a misbranded condition. We do not know of any products being produced for general use to military or other federal specifications that are in conflict with the food-additives amendment. Upon request of other government agencies, the FDA reviews and comments on their proposed food or container specifications.

Question.—Would the FDA members of the panel comment on the advisability of members of the pigment industry pooling their

technical staffs in a joint effort to attack their common problem? *Answer.*—It would seem to us that this is a question to be answered by industry rather than the FDA. If the industry can pool its information without revealing trade secrets or running afoul of the antitrust laws, we should think it would save considerable time and effort by doing so.

Question.—Will or should foods irradiated by isotopes or electrons be cleared for consumption? *Answer.*—Foods preserved or pasteurized by radioactivity have not yet been cleared for commercial shipment. Whether they should be cleared will depend upon whether adequate research studies establish the safety of the irradiation and whether the treated food is in all other respects in compliance with the Food, Drug, and Cosmetic Act.

Question.—Are there any means whereby the concept and the enforcement procedures of the food-additives amendment are applied to products manufactured, processed and packaged in other countries and shipped into the United States to compete with American products? *Answer.*—The Food and Drug Administration regularly examines, on a spot-check basis, samples of foods offered for importation into the United States. Imported foods will be examined within the limit of our facilities for residues of food additives.

Question.—May an additive which has not been cleared for use by the FDA be considered food which has been adulterated in violation of the food-additives amendment? *Answer.*—The term "food" is defined in the Federal Food, Drug, and Cosmetic Act to mean, among other things, "articles used for components of" food. Thus, it is apparent that a food additive would be food within the meaning of the law and would be subject to the adulteration provisions of the law.

Question.—Is a dye marking, a mineral oil or a wax coating of eggs considered a food additive? *Answer.*—If the substance is not generally recognized as safe by appropriate experts and does not have a prior sanction. Also, in the case of the dye, if it is not a coal-tar color. (Coal-tar colors are covered by the coal-tar-color section of the food chapter of the law and not the food-additives amendment.)

Question.—Will exception to Section 201(s)(3) of the additives amendment pertaining to sanctions by the Meat Inspection Division of the Department of Agriculture permit use of the substance or additive in *any* product or only in meat products? *Answer.*—Only in the meat products covered by the MID sanctions.

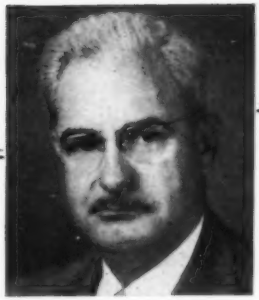
What Can Industry Do to Help Solve Problems of Antibiotics and Insecticides?

ORDINARILY, APPEARANCES before laboratory and technical sections of conventions such as this are made by technical people —at least, it is the general practice in the Food and Drug Administration to do so. I am particularly pleased at this opportunity to appear before you in place of a representative of the Food and Drug Administration's Division of Food.

While, for many years, my duties have been primarily in administrative and enforcement areas, I have had some experience in the technical aspects of the work of the Food and Drug Administration. I am not wholly unfamiliar with the practices and problems that prevail in field-inspection work and in laboratory operation and management.

The title of my article, I think, evidences the cooperative spirit of the milk industry in its approach to problems where the Food and Drug Administration is involved. To the extent that we can jointly solve these problems without unnecessary general publicity, the best interests of both the industry and the public will be served. We do regard the problems of antibiotics and insecticides in milk as serious.

First, I should like to briefly touch upon the inquiries and investigations that we have made into the problem and then to discuss what we are doing and intend to do, and what, in my view, the industry can do. In 1954, we examined 94 samples of milk in different areas and found that 3 per cent of them contained penicillin. In 1955, 474 samples showed 11.6 per cent containing penicillin. In 1956, 1,706 samples were examined and 6 per cent contained penicillin. With the facts from these surveys before us, we undertook a searching inquiry among experts in the medical field to ascertain as accurately as possible whether, from the standpoint of threat to the public health,



By JOHN L. HARVEY

The Deputy Commissioner of Food and Drugs Delivered This Speech Before the Milk Industry Foundation, at Miami Beach on October 8, 1959

these facts showed a serious situation. A group of internationally known physicians, together with a number who are primarily in the public-health field, considered all of the aspects relating to the presence of antibiotics in our fluid milk supply. The essence of the conclusions of this group was that while antibiotics in general should not occur in our milk supply at all, the presence of penicillin in the milk supply represents a pressing public-health problem.

Treatment of Mastitis with Penicillin Preparations

It is recognized that the presence of penicillin in fluid milk results primarily from the use of penicillin preparations in the treatment of mastitis. It is also recognized that mastitis is one of the most important of the diseases that affect milk cattle in the United States in an economic sense. It is therefore apparent that the use of penicillin for the treatment of mastitis is a tremendous boon to dairy production. If penicillin cannot be made available, the effect upon the dairy industry will be significant.

There are two philosophies which people tend to apply to problems of this kind. One view is that if there is a danger in a food-producing practice, that practice should be prohibited regardless of the economic or other consequences of the prohibition. The other view is that where it is possible to permit the practice under controls and restrictions that will reasonably assure its safe use, the best public policy is to permit use under such regulation. I think it is fair to say that the public policy in the United States with regard to our food

supply is best reflected by the acts of Congress covering the subject of food regulation.

One may conclude that we have long since turned the corner on the prohibition route and, as a nation, have decided that there are many aspects of modern civilization which offer a hazard to health and welfare but which can be adequately controlled so that their benefits can be enjoyed. We have elected to follow this pattern.

Essential Philosophy of Law

There are circumstances, of course, in the food field in which prohibition of certain practices or ingredients is the only safe course. It has been urged upon the Food and Drug Administration that the only solution to the penicillin-in-milk problem is to bring about a discontinuance of the use of penicillin in the treatment of mastitis. The law is broad enough to permit this remedy. It is, however, my view that the essential philosophy of the law is that such prohibition should not be the remedy of choice unless it is conclusively shown that use with regulation cannot adequately protect the public interest.

We, in cooperation with the Extension Service of the United States Department of Agriculture, the National Milk Producers Federation, and others, undertook a widespread campaign of education of the dairy farmer both in methods to aid in the prevention of the occurrence of mastitis and in the use of penicillin in treating mastitis when it does occur. In the latter circumstances our efforts were directed primarily at education as to the need for discarding milk from treated animals for an appropriate period of time following the last treatment with penicillin.

We amended our antibiotics regulations to increase conspicuousness in the labeling of pencillin products used for the treatment of mastitis as to the requirements for discarding milk. Later, we took steps to limit more sharply the amount of penicillin contained in doses for intermammary infusion. This limitation was placed at 100,000 units per dose, which represented a significant change from the previously used preparations, which contained as much as 1,500,000 units per dose.

We allowed a reasonable time for the effects of these various steps to be noticeable and then planned an investigation of market milk involving 16 of our field district offices and covering a period of four months in the fall of 1958. In this we had excellent cooperation from the officials in the dairy control areas of the different states. Our setup was such as to give uniform sampling across the country.

Of the 1,170 samples thus obtained and examined for penicillin, 3.7 per cent were positive. This justified the conclusion that our educational activities had resulted in a noticeable reduction in the occurrence of penicillin in the milk samples in 1958 as contrasted with the 1955 and 1956 surveys. Unfortunately, however, it does not demonstrate that the problem has been solved by educational means alone nor are we able to conclude that it will be so solved.

It may be said at this point that taking all these facts into account, the Council on Drugs of the American Medical Association called upon the Food and Drug Administration to "get penicillin out of milk."

Now, while this work on antibiotics in milk was being carried on, we were obtaining data on pesticide residues in market milk. In 1955 we conducted a nation-wide survey of market milk for pesticide residues. Because we were in the process of developing analytical methods, the results on most samples were only semiquantitative. However, quantitative chemical tests on 169 samples believed to have highest insecticide residues (based on earlier bioassay) showed 33 samples with residues ranging from 0.05 to 1.5 parts per million of DDT or its equivalent.

Safer Use of Pesticides—Educational Campaign

In the same manner as with antibiotics in milk, we undertook to promote an educational campaign to aid in safer use of pesticides on dairy farms. We again had excellent cooperation from the United States Department of Agriculture and from the states and the milk-industry associations. In the 1958 survey, 936 samples of milk were examined for pesticide residues, and 2.5 per cent were found to contain significant residues. These included DDT, DDD, toxaphene, chlordane, and BHC. Again, we were forced to conclude that educational measures are a great help but not a complete remedy.

I should mention that, in addition to the evaluation of the problem made by the Food and Drug Administration, an advisory committee of the National Research Council gave lengthy consideration to a proposal for tolerances for pesticide residues in milk. The conclusions of this advisory committee were such as firmly and flatly to urge that no tolerances for pesticide residues in milk should be established.

With this background statement, it is fitting that I now come to discussing the title of this paper. What can you in the milk industry do about these problems? I think there is much that you can do, and I have every reason to believe that you will do much.

Addressing ourselves first to the penicillin problem, I am pleased to be able to tell you that we in the Food and Drug Administration have developed a practicable and more rapid test for the detection of the presence of antibiotics in fluid milk than we have heretofore been able to offer. Instead of taking a day or two to complete an examination of a single sample, we can now produce results in about 2½ hours. This method, published in the October, 1959 issue of the *Journal of Milk Technology*, is available; the Food and Drug Administration will provide copies to all who ask for them.

I do not apprehend that the use of this test should cause any more difficulty in industry and state and federal control than the various not-too-complicated bacteriological tests which you routinely perform in industry control operations. It is true that evaluating the results of these inhibitory tests requires some training and skill, but it is not difficult or complicated. Essentially, the method involves the same principles that have been used heretofore, but results are arrived at much more quickly by the better selection of organisms.

Chemical methods for pesticide residues have not been improved so much as the antibiotic method, from the standpoint of simplicity of operation or of speed. Available methods can be run by competent chemists with properly equipped laboratories, and we can and will supply, on request, references to the methods in use.

I can foresee some consternation in your minds at the idea, as a part of production, of having to examine samples for penicillin and pesticide residues from each lot of milk received in your plants. I hasten to say that I am not suggesting nor recommending that such a program of testing be undertaken or that it will ultimately be proved necessary. Every fluid milk establishment has field men and I am sure that their competence has not changed significantly since the days when I was a food and drug inspector. I was constantly amazed at the amount of information field men possessed as to what goes on on the farms—not only on the farms of their own patrons, but many times on the farms all around the countryside. These field men know which milk producers are having trouble with mastitis and I would think that in most instances they could guide plant management in sampling operations. I doubt that performing this function would impose any particular burden on field men, or be anything out of line with their normal operations.

I am not at all sure that field men serve as reliable guides to sampling for pesticide residues. They can do a great deal as educators

to help in making sure that the patrons are properly using pesticides in the dairy and on the cows and are taking such precautions as they can to avoid the feeding of forage contaminated with pesticides. I recognize that it is quite a problem for farmers who purchase feed in open markets to be sure that fodder purchased is not contaminated with pesticide chemicals that might get into the milk and I believe that both state and federal checking on this phase of the problem will have to be stepped up.

FDA Regulatory Program Outlined

Now, the last thing that I have in mind is standing before you and waving a big stick, but I do want to emphasize that accepting and shipping milk which is contaminated with antibiotic or pesticidal residues can lead to serious trouble. Such milk is clearly adulterated within the meaning of the Federal Food, Drug, and Cosmetic Act, and we must find ways to avoid violations. Any program that you undertake along the lines suggested would take into account what the Food and Drug Administration, and regulatory agencies generally, may be doing. At this point I should tell what we are doing and what we intend to do.

Beginning in October, 1959, inspectors of the Food and Drug Administration stepped up a program of investigating the production of fluid milk in various areas of the country. Samples are being collected for examination for antibiotic and pesticide residues from shipments in interstate commerce or offered for interstate shipment. We shall examine the samples, using the procedures that I have mentioned earlier, with identification specifically of penicillin where positive results are obtained. Where our examinations of such samples show the presence of penicillin or pesticidal residues, it will be our purpose to institute appropriate legal actions as provided by law. I would think that the first actions would involve seizure of adultered milk. Whether injunction actions and criminal procecutions will be applied depends upon developments. This regulatory program has the definite objective of eliminating antibiotic and pesticide residues from milk to the extent that we can, with our resources, bring about such a result.

Our jurisdiction is limited to interstate commerce, and obviously the problems cannot be solved by regulation only of interstate milk. We will discuss our positive program with state and local milk control officials, and we sincerely hope that we will be able to see concurrent steps being taken by them to apply controls to adultered milk

which does not enter channels of interstate commerce. This type of cooperative approach among state, local and federal officials has been outstandingly successful in correcting problems in the past, and it can be in this instance.

We recognize that some of the state and local officials may not have experience in the field of testing milk for pesticides and antibiotic residues. Our organization in Washington is prepared to work up a training program which will contemplate a number of regional seminars or schools, if you choose, and these will be set up, if there is a demand, to provide state and local enforcement people with training in the methods which we employ. I am sure that in any training endeavors that we and the state people undertake, methods can be found to afford some technicians from industry an opportunity to secure such training. Our first obligation is to make training available to our counterparts in state and local enforcement organizations, but we are not unwilling to consider giving similar help to industry within our resources.

In conclusion, I sincerely hope that the remarks that I have made cannot be construed as in the nature of a threat, but only as a frank discussion with a sincere hope that the efforts of industry will minimize the need for any regulatory actions. It is incumbent upon industry to proceed without delay to eliminate these dangerous contaminants from the milk supply and to provide only milk which is the clean and wholesome article that the public expects it to be. With the same spirit of fine cooperation that has existed between our industry and government regulatory officials for a great many years, I am confident that the milk supply can be cleaned up in this respect without delay, and that the blessings and advantages of our modern systems of treating disease and of protecting our crops and our animals can be continued on the basis of containment by adequate precautions and that amount of positive regulation which insures adequate precautions.

[The End]

• "EGGLEGGERS" RECEIVE JAIL SENTENCES •

Three defendants accused of diverting rotten incubator-reject eggs into food use were each sentenced to four months in jail, and fined $250 as well, on March 15 by the federal court at Nashville, Tennessee. Two other defendants were given suspended sentences and three years' probation.

In another jurisdiction, the federal court at Miami, Florida, sentenced an individual to six months in jail and fined him $500 for shipping rotten frozen whole eggs. This prison sentence was suspended and the defendant placed on five years' probation.

SAFETY OF PACKAGING MATERIALS

By J. KENNETH KIRK

The Author Serves as Assistant to the Commissioner, Food and Drug Administration, United States Department of Health, Education, and Welfare. His Paper Is Derived from an Address Given at the Twenty-first Annual Packaging Institute, in New York City on November 18, 1959

A SHORT WHILE AGO, a man representing a packaging-material group came to Deputy Commissioner Harvey with a complaint. He stated that he had attended a packaging meeting where a member of the FDA staff had presented a paper on the food-additives amendment to the Federal Food, Drug, and Cosmetic Act which had shocked both the group and this man personally. His attitude was that he just could not understand a government official's talking "that tough" to a group of businessmen and that the net result of the talk was that the manufacturers had gone away scared.

The complainant expressed even more surprise when he was told that the paper under discussion had been made deliberately tough, and had been approved because it seemed that some segments of the industry had not adopted a forthright attitude of trying to comply with the amendment and that such a jolt might bring home to them that this food-additives amendment is the law of the land. It was our hope that this sort of plain talk would get the ball rolling, and stop the group from maintaining the attitude that if they paid no attention to the problem, it would just go away.

I don't know whether it was that kind of talk—or what it was—but certainly something has served to impress on the packaging industry that things must be done. We can already see the results in Washington.

I don't propose to stand here today with a "get tough" attitude, but frankly I was greatly surprised that such a step on our part was necessary in the first place. After all, the food-additives amendment procedures are really nothing new to many people of the packaging industry. They have been coming to us for years with problems of what migrants were getting into the food supply, and they took steps to be sure that these were safe. Incidentally, those who did so, even without a clear-cut requirement in the law prior to the enactment of the food-additives amendment, now find themselves in a most enviable position—they have prior sanctions for the items cleared in the past.

Reminder of Fundamental Principles

As we see it, there are two fundamental principles which may well have been overlooked by some in the packaging industry:

The first of these is the matter of just what we should be talking about when we deal with the food-additives question. Certainly, initially we are not dealing just with the finished package. Instead, we are concerned with such of its individual components, added as such, or produced by reaction during the process, which are not generally recognized as safe by experts qualified by scientific training and experience to evaluate their safety and which may reasonably be expected to migrate to the food.

As a basic premise, therefore, it is of paramount importance to learn first just what components go into the package, and what ones are there when it is ready to be used. At that point, knowing what types of foods are to be in contact with the package, it is time to consider migration studies. As we have said, we know that in most instances no one firm starts out with all this information, so it must be a case for cooperation between the raw material suppliers, the package manufacturer and the food manufacturer. Incidentally, if migration studies are necessary, we have methods whereby this can be done with solvents whereby the actual foods are not used. Descriptions of these methods may be obtained by writing for them.

The second principle is getting away from the idea that there is no real problem in the packaging field because of the belief that the amounts of the packaging components that may get in to the food are small. In this connection, we have been asked if we do not recognize that we should take the position that the incidental additives from

packaging materials be classed as *"de minimus"* or of "pharmacological insignificance." While these are nice-sounding terms, the fact remains that we just are not in a position to solve our food-additives problems on the basis of semantics.

When you come right down to fundamentals, the proponents of this idea are really asking that we deal with these incidental additives on a basis clearly different from that contemplated by the law. They are saying that we should, in effect, set tolerances for incidental additives by a sort of short-cut procedure—just because the additives are present in quite small quantities. When we take a good look at this proposal, we find that in essence we are being asked to decide that a small quantity of Substance X is to be regarded as safe, when in some cases we are not sure just how much of Substance X may reasonably be expected to migrate to the food. Even when we do have information on that score, we do not know what the toxicity of Substance X actually is. When I talk of toxicity, I am including chronic toxicity as well as acute. The fact that the product may have a relatively low acute toxicity is not the answer.

Importance of "No Effect" Level

It just is not possible to set up a tolerance (or decide that one is not necessary) without first having facts about the toxicity of the particular substance and—what is very important—the so-called "no effect" level found on feeding the product over long periods of time. Once we have this information about Substance X before us, we can determine whether the limit proposed is a safe one for the establishment of a formal regulation under the amendment or whether, as may well be the case, the amount involved is generally recognized as safe. When you try to do this without the basic toxicity data, however, you are working in a vacuum and, in our opinion, have no good chance of succeeding.

Certainly, one or two parts per million of a food additive doesn't sound like very much; with many substances used in our food supply, it isn't. On the other hand, with some substances, one part per million may well be too much, based on the toxicity and no-effect level of the substance. Of course, if the additive has been shown to produce cancer on ingestion or when tested by other means appropriate for testing food additives, it may not be present in the food in any amount.

While I have tried to demonstrate why we cannot set a tolerance, official or unofficial, for a food additive of unknown toxicity, I do not mean to imply that complete lifetime studies are going to be required for each incidental additive from packaging material. By the same token, I do not mean to imply that we are going to require, in every case, an analytical method of such sensitivity as will detect that last molecule of it in food. Instead, we believe that where there is enough toxicity data available, our scientists may well be able to suggest the sensitivity of the method needed to determine whether any of the substance is present. Where this is done and where the substance is found by that method to be present, it is obvious that complete toxicity data will be needed.

Regulations Policy Under Amendment

At this point I should stress, too, that the food-additives amendment does not contemplate the issuance of regulations for the various food additives where there is no practical means of enforcing the provisions of those regulations. There is, for example, nothing to be gained by setting a tolerance for a food additive at, say, two parts per million in the food if the best analytical method available will not detect less than ten parts per million.

At the same time, however, we recognize that it just may not be possible to develop a practical method for a particular food additive, and we have indicated our willingness to consider other approaches to the problem in those instances. The polypropylene petition now before us is a case in point, where the control is proposed in the specifications for the substance in the package itself. We are still working on that petition, but hope to be able to announce our decision soon.

Error of Overgeneralization

I think that we all make a mistake when we start to generalize too much in this field of packaging-material food additives. When we do, we hear of the tremendous problem because of the hundreds of materials that *may* be used and hear the claim that there seems to be no real starting point. Instead, we would advocate getting down to cases on an individual formulation basis.

If this is done, it can be determined just which components need be considered from the standpoint of safety. Perhaps some of the components can be ruled as safe and, thus, need no more concern. Perhaps some have prior sanctions; if so, the information is available on request.

Don't hesitate to discuss your problems with us as you go along —we want to be as helpful as possible. Then, too, unless you have a lot of experience in this particular field, we advise against going ahead with expensive testing programs until you've talked over the situation with our technical people. You might well find that some of the work you've planned is not at all necessary—maybe someone else has already done it.

Extension Provision—Importance

The Act does, of course, provide for extension not to exceed one year, provided the Secretary of the Department of Health, Education, and Welfare can be satisfied that such an extension would not present any hazard to the public health. This, however, is a very important proviso and we have been urging people *not* to count on blanket exemptions, since it seems obvious that the Secretary could hardly decide that something would present no hazard to health when he knows nothing about the toxicity of the substance or how much of it might be in any particular food.

Don't sit back and do nothing in anticipation of an extension. That is the best advice that can be given at this time. **[The End]**

VOLUNTARY-ACTION PROGRAMS AID IN CONSUMER PROTECTION

According to the Food and Drug Administration's April report on enforcement and compliance, in 16 individual plant improvements made during March, 1960, to assure production of clean, wholesome products, food manufacturers and warehousemen spent a total of $72,736. Six hundred and twenty-two tons of unfit food products were prevented from reaching consumers because their owners—in 61 additional voluntary actions—destroyed or converted them to nonfood use. Large individual expenditures included a California nut packer's $26,000 voluntary plant-improvement program; a Minnesota creamery's $16,000 program to prevent possible contamination of milk received from purducers; and a West Virginia wholesale grocer's $8,756 program to prevent possible rodent and insect contamination of stored foods.

Drug firms destroyed old and substandard drugs valued at $39,783.

By GEORGE P. LARRICK

Status of Food-Additives

Commissioner of Food and Drugs Larrick, Examining a "New Law of Broad Import," Points Out That It Isn't the First Time That There Have Been Deadlines When Firms Have Had to Meet New Requirements. His Article Is Taken from a Speech He Delivered Before The Food Group, in Washington, D. C., January 27

I WAS PARTICULARLY PLEASED to have this opportunity of talking with you because it gives us a chance to consider together the status of food-additives control somewhat more than a year after the food-additives amendment became law. When legislation as important as this is enacted, it is imperative, we believe, to take stock periodically as the law goes into effect and be sure that its administration is proceeding as intended. It probably would be equally important for the regulated industries to take stock at frequent intervals to be sure that they are aware of the latest developments, and have taken such steps as are necessary and possible to permit the new law to become operative with a minimum disruption of industrial processes.

What Has Been Accomplished Since Law's Enactment

Perhaps the first thing we should do is to look back over the past 16 months to see what has been done since the amendment was signed by the President on September 6, 1958. Have we really accomplished much in these 16 months—or do we find ourselves at about the same place we were late in 1958?

The first job we in the government were faced with was that of obtaining money to support the additional work required by the amendment, securing staff to handle the job, and drafting procedural regulations that would guide us and industry in dealing with matters that came up under the amendment. All of these tasks have been accomplished. As you know, we got the supplemental appropriation we requested. We assigned staff to the administration of the law almost immediately after its enactment, and the procedural interpretive regulations have been effective for many months.

Control

There have been many hundreds of contacts with consumers, industries, other government agencies—in fact, with virtually every element of our society that is concerned with the use of chemicals in foods. These contacts have been through interviews, correspondence, speeches made by FDA personnel, pamphlets prepared by our Division of Public Information, etc. We hope that our efforts in this regard have contributed to a wider knowledge of the requirements of the food-additives amendment and of the procedures for having food additives cleared.

Procedure for Determining Scientists' Views

We worked out a procedure for canvassing a group of representative scientists in the various disciplines involved in the food-additives amendment to determine their views about the safety of chemicals used in food. This, of course, was to enable us to determine what they thought about the safety of a number of substances that had been used for foodstuffs in the past—that is, whether they generally recognize these substances as being safe. The method we worked out may not be perfect. We know that some of you believe that it could be improved in some respects and we will be glad to have your suggestions for improvement at any time, but the method is workable. Under it we have been able to publish two lists of substances generally recognized as safe in foods. Other lists are in process at this time.

There are many chemicals so generally recognized as safe that we have not placed them on a list and do not expect to. Such things as salt, sugar, cottonseed oil, and the like do not need to be placed on the list. Combining these steps, it is apparent that the status of several

hundred commonly used chemicals has already been established under the new law. It seems likely that clearance of most of the other chemicals (except for those already proposed for incorporation in a list of substances generally recognized as safe) will be by the petition route rather than the general-recognition-of-safety route.

Misunderstanding Concerning Listing of Substances

One development here is interesting. Some people obviously do not understand the workings of this new law; they have concluded that unless a material appears on a list of substances generally recognized as safe, it is automatically banned from food. I am sure you are well aware of the reaction in the press to the fact that carbon black was not included in the first list that we published. Our failure to include it after it had been incorporated in the tentative list published earlier did not mean at all that carbon black has been found unsafe. It simply reflected the fact that some of the competent scientists who wrote us said they did not have a basis for regarding "carbon black," unqualified, as safe in food. They knew that under some methods of manufacture the compound might be contaminated with toxic impurities. They had no question about the safety of pure carbon. So we concluded that it would be necessary, before recognizing carbon black as a suitable ingredient in food, to ask the manufacturers to suggest specifications for a compound suitable for food use that could be incorporated in a regulation sanctioning the addition of this product to foodstuffs. The effective date of the amendment has already been extended, with respect to carbon black, to allow time for the development by its producers of appropriate specifications.

We left oil of wintergreen off the flavoring list published recently. This was done because we have tests under way in our laboratory right now in which the effect of oil of wintergreen on laboratory animals is being studied. When they are completed in about a year, we will have the facts upon which to re-evaluate the oil. Meanwhile, we have no reason to question the current use of oil of wintergreen as a flavor nor any intention of taking regulatory action because of the facts now before us; we hope that the food industry and consumers generally will accept the statement we made in the *Federal Register* about oil of wintergreen. There is no basis that I know of for any alarm on this subject.

To get back to the progress that has been made under the new law, we have handled a few petitions and the flow of petitions has

increased tremendously as March 6, 1960, approaches. We have developed a procedure for evaluating requests for extension of the effective date of the law, anticipating that in a number of cases firms will find it necessary to ask for additional time and will be able to show that the extensions are necessary and, in the words of the law, will involve "no undue risk to the public health."

There has been a lot of progress made in industry, too. Many associations and other industry groups have conducted widespread educational programs to acquaint their members with the requirements of the new law. A number of groups have taken the lead in compiling data that would be useful to them and us in determining the application of the law to their products. I have in mind, for example, the very extensive studies that have been sponsored by the Flavoring Extract Manufacturers Association. We know also that for some months many individuals firms have been compiling the data needed to support their petitions for sanctions on specific food-additives uses.

I think you will agree that while there is still a lot to be done, there have been major accomplishments during these first few months. It is important that none of us belittles our accomplishments.

Government's Workload of Correspondence, Consultations, Petitions

For the future, we in the government have a very heavy workload of correspondence, consultations and petitions generated by the new law. The status of additional products under it needs to be determined. In general, the firms that were accustomed to working with us before the food-additives amendment was enacted have made more apparent progress than some of the industries that were not. We gained the impression that the latter group got started slowly, but it is evident that everyone is now becoming aware that there is a job to be done and almost everyone is striving to get it accomplished. This may be due in part to the fact that some of the users of food additives are demanding guarantees from their suppliers that the additives do meet the requirements of the law. That sounds like good business to us.

The next question that comes up is: What are we going to do about the chores yet to be handled under this amendment? We have heard some wild rumors in the last few weeks. Some people are predicting that the new law will wreck the food business generally or the

packaging business or the food-equipment business, but we haven't seen any evidence that this is the case. Some people have suggested that the situation is so critical they must go to Congress immediately and get an extension of the effective date of the law. There have been some problems resulting from the Delaney cancer clause and there are some suggestions that this clause be deleted by legislative action.

Brief Review of Situation

Let's look at the situation briefly. This isn't the first time that the Food and Drug Administration has administered a new law of broad import. It isn't the first time we have been approaching deadlines when firms had to meet new requirements. The 1938 law placed many new requirements on food, drug and cosmetic industries. The cosmetic industry, particularly, which had not been subject to the old 1906 law, faced the 1938 law with trepidation. There were some rough spots but hindsight shows that the 1938 statute went into operation rather smoothly. A glance at the balance sheets of the food, drug and cosmetic industries fails to show that they were wrecked, even temporarily, by it.

A number of amendments to this basic statute have been passed since 1938. One in particular, the pesticide-chemicals amendment, placed upon pesticide chemicals safety-testing requirements quite comparable to the clearance requirements that now exist for food additives. That law was just as important to relatively few manufacturers as is the food-additives amendment to relatively many, and it went into effect smoothly. There was no catastrophe. Pesticide chemicals stayed on the market and, in general, the same firms are marketing them as were in business before 1954.

No Indication of Impending Economic Upheaval

I expect that there will be some changes when the food-additives amendment becomes fully effective, just as the other laws mentioned required changes in business practices. This was recognized when Congress passed the law in the first place. It was intended to bring about changes in the situation then existing, but we have seen no indication that there is going to be an economic upheaval when this amendment becomes fully effective or that all foods or all packaging materials or all food machinery are going to be taken off the market or even that a major portion of these materials will be seriously affected. A firm still has the right to decide for itself whether its

product is subject to the food-additives amendment and if the firm thinks it is not, we have the obligation of proving in court that it is before we can maintain actions against the product or the firm. We have announced—as noted above—the procedure whereby extensions of the effective date of the law for up to another year can be granted. I believe that the American people will continue to get adequate food without wild alarms and without mass seizures by the government of food additives that hadn't been cleared. In short, we expect the world, immediately after this law becomes fully effective, to continue to operate about the same way as it does now.

We have no basis for recommending that Secretary of Health, Education, and Welfare Arthur S. Flemming support legislative action to grant further extensions of the effective date. The government now has the power to grant up to a year of additional time by administrative action. It seems unlikely that Congress would be receptive to requests for legislation to extend the effective date of the law when the situation is amenable to control by administrative action.

There is every indication that, with continued strong industry-government-consumer support, this law will get under way smoothly. We appreciate the assistance most of you in this room have rendered in implementing the statute and we request your continued support of it and us in the future. **[The End]**

ADMINISTRATION REPORTS COURT ACTIONS DURING MARCH, 1960

Twelve of the 23 drugs and devices seized during March, 1960, were alleged to bear false and misleading claims, the Food and Drug Administration reported in its April summary of enforcement and compliance. Seven actions were taken against so-called "food supplements" in a continuation of the government program against products promoted by false or misleading statements which suggest or imply that available foods do not meet nutritional needs and that the average person must supplement his diet with these products.

A milk-powder concentrate containing calcium, phosphorus, protein and lactose was offered as a treatment for intestinal disorders including toxemia, stagnation and constipation. Offered for weight reduction and also alleged to be misbranded were three brands of capsules containing an alleged "appetite suppressant," phenylpropanolamine hydrochloride, which is not effective for controlling the appetite. Two vibrator-massage devices were also offered for weight reduction.

Rodent contamination in carload shipments caused the seizure of 278 tons of wheat and flour. The total quantity of unfit foods removed from the market during the month was 575 tons.

Altogether, 77 food and drug seizure actions were instituted in the federal courts during March.

Additives Legislation Affecting F

By J. KENNETH KIRK

Assistant to the Commissioner of Food and Drugs

IT IS A PLEASURE to meet with this group today. We sincerely hope that out of such meetings as this will come a clearer understanding of just what responsibilities are placed on both industry and government under our present laws.

I will first discuss additives legislation dealing with cosmetics. All cosmetics moving in interstate commerce, including those offered for import from other countries, are subject to the basic provisions of the Federal Food, Drug, and Cosmetic Act. The cosmetic section of this law has remained essentially unchanged since its enactment in 1938, so perhaps we need not discuss these provisions in detail now. Developments in recent years which have shown certain weaknesses in this law, resulting in real injury to users from some cosmetics products, have pointed up the need for strengthening the law by a requirement for pretesting of cosmetics prior to their being marketed.

Originally, the need for such legislation was discussed in the reports of the hearings held by a committee of the House of Representatives several years ago. Two bills dealing with this subject are currently pending before the Congress and the subject is being given extensive consideration by the United States Department of Health, Education, and Welfare.

Those of you who deal with the cosmetic industry are, of course, well aware of the urgent need for color-additives legislation. A color-additives bill was passed by the Senate just at the close of the last session of Congress, and the House Committee on Interstate and Foreign Commerce has scheduled hearings on the color-additives bill to start January 26, 1960.

Coming now to the first part of the suggested title of this discussion, we have, as you know, the food-additives amendment to the

Foods and Cosmetics

Mr. Kirk, Addressing the Fatty Acid Producers' Council on January 20 at New York City, Stressed Value of Government-Industry Cooperation

Federal Food, Drug, and Cosmetic Act, enacted in September, 1958, and scheduled to become fully effective on March 6, 1960, subject to one-year extensions of the effective date for specific substances, which we will take up later. This amendment has a very definite bearing on fatty acids and their derivatives used, or proposed for use, in our food supply.

Those of you who took courses in biochemistry 20 or 25 years ago will recall that the section on fats was undoubtedly the skimpiest in your textbook. The most important reaction of fats was their hydrolysis to fatty acids in the body. Fatty acids, although utilizable for energy by the body, were thought to be relatively unreactive materials, much like hydrocarbons. In the last 25 years, however, there has been probably no field of food technology which has grown at a more rapid pace than that of the fat and oil industry.

About four or five years ago our scientists began noting the increasing frequency of references in literature to reactions which fats and oils undergo on heating. Looking into the matter more fully, they found sporadic references to the possible formation of toxic materials from heated fats. We set some of our chemists to work to investigate the changes in the chemical, nutritional and toxicological properties of heated fats. During a period of approximately two years they obtained the necessary equipment, prepared several batches of overheated cottonseed oil, separated them into a number of fractions, and discovered that some of these materials, when fed to rats, would kill them. The toxic fractions were characterized as monomeric and dimeric substances that do not form complexes with urea.

Just about this time when we were prepared to expand our investigation into the physiological properties of heated fats and their chem-

ical composition, the rather spectacular chick-edema disease episode occurred. This problem, as some of you will recall, consisted of an outbreak in the broiler industry of a fatal disease with the striking symptom of swelling of the abdomen due to accumulation of fluids. It was soon traced to the use of a by-product of the fat-splitting industry. We recognized immediately that this was a special aspect of our heated-fat problem.

The toxic fatty products were found to contain very large quantities of fatty acids that did not complex with urea and that were toxic to weanling rats. Although this material depressed the growth of chicks it did not produce chick-edema disease. The chick-edema factor was not present in the fatty-acid fraction, but in the unsaponifiable residue. For the past two years we, as well as several other laboratories, have been endeavoring to isolate and identify the toxic component. The material is so extremely toxic that "purified" fractions, though still impure, cause symptoms when fed in amounts measured in fractions of a part per million.

With the cooperation of several manufacturers of fatty acids, we obtained several series of samples and have determined that the edema disease factor is present early in the manufacturing operations of the production of fatty acids. This phase of our investigation was by no means systematic or complete but it immediately brought us to a realization that we were dealing with a potentially serious situation. Our inspectors were reporting more and more the presence of fatty acids in food-manufacturing plants, often in combination with other materials as emulsifiers and stabilizers. Various segments of the food-packaging industry were reporting to us the use of fatty acids and their derivatives in their containers.

It became apparent, after the passage of the food-additives amendment, that fatty acids constitute a significant part of the total tonnage of food additives which would be consumed in this country. Most of these fatty acids were oleic and stearic acids and, during the course of our experimentation with various industrial supplies of oleic acid, we encountered several oleic acids which contained the chick-edema disease factor. In fact, a sample of triolein had been reported to us to kill monkeys. When fed to chickens in our own laboratory it produced the chick-edema disease, and it is an excellent source of material for further work on the isolation of the toxic factor.

Although circumstantial evidence indicates that the chick-edema disease-producing factor is even more toxic to monkeys, final proof

of this must be obtained by feeding purified concentrates to monkeys. There is also some scanty evidence, based on feeding crude sources of chick-edema disease factor, that rats and dogs are susceptible.

If a sample of triolein contains this potentially toxic material we could naturally assume that samples of oleic acids, although of very high purity by customary standards, could also contain the toxic factor. This possibility was verified by the finding of the chick-edema disease factor in several samples of oleic acid from various sources by our laboratory and also by other industrial laboratories that have examined oleic acid by the same toxicity methods.

We have examined two stearic acid samples. Although both of them were negative for the factor, this can hardly be assumed to be a satisfactory sampling on which to base a conclusion that stearic acids do not contain the chick-edemâ disease factor, particularly since some of the first distillates, used for stearic acid production, which we have obtained at the factories do contain the chick-edema disease factor.

At about this time, food manufacturers became aware of the necessity for obtaining "clearance" of materials used in foods which may fall under the jurisdiction of the food-additives amendment to the Federal Food, Drug, and Cosmetic Act. The Food and Drug Administration published in its proposed "white list" of December, 1958, a number of materials generally recognized as safe. Included in this list were oleic and stearic acids. However, there were, in the minds of a number of investigators of the safety of commercial oleic acids because of the presence of toxic materials, sufficient doubts to raise the question as to whether or not fatty acids commercially available for food use could be generally recognized as safe in the absence of specifications.

This presented a rather unusual situation, since we are convinced that all scientists recognized oleic and stearic acids as the chief constituents of our natural fats and oils. How could they be anything but safe? It is therefore extremely important to make clear that we do regard oleic and stearic acid per se as safe.

We must recognize, however, that when fats have been subjected to such tremendous temperatures and pressures as are characteristic of our industrial fatty-acid operations today, profound changes occur which result in the production of small amounts of toxic materials. Either raw materials or processes may be responsible for the presence

of a material which accompanies the oleic acid and, possibly, the stearic acid which are now sold to food processors for use in foods. When we discover what this substance is and devise a chemical test or, if necessary, use the bioassay test for this material, then fatty acids can be used in foods under specifications utilizing these tests.

We do know that the present specifications which determine quality in this field are not satisfactory. Iodine number indicates stability and degree of unsaturation; color indicates suitability for special food use; melting point is related to texture. We are thinking here in terms of the more difficult types of chemical determinations which are not so routine in the chemical laboratory, such as unsaponifiable material and hydrocarbon content of the unsaponifiable material; completeness of hydrogenation; the content of fatty acids which do not adduct with urea—that is, branched chain and cyclic types of fatty acids which may be present through thermal decomposition or which may have undergone other types of chemical changes.

For many years the Food and Drug Administration gave little attention to the fat-splitting industry. On the rare vists of one of our inspectors, he usually would encounter the statement that this industry was not part of the food field and that most of its production went to industrial fatty-acid uses. This statement was undoubtedly true but, with the advent of the food-additives amendment, more and more of these industrial fatty-acid processors have discovered that they do have customers in the food field for products of their highest quality. Unfortunately, it now appears that some of U. S. P.-or-higher grades are not now of food quality because of the presence of a toxic material.

From this discussion it will, I believe, be apparent to this group why the Food and Drug Administration is not in a position to make any generalization that fatty acids and their derivatives now on the market are to be classed as being generally recognized as safe. On the contrary, we see no alternative but to hold that they are food additives. As such, the issuance of appropriate regulations are called for by the terms of the food-additives amendment.

We have no illusions that it will be possible to issue such regulations prior to March 6, 1960. Neither, however, do we feel that the situation is such as to call for the discontinuance of these substances from our food supply as of that date. As already mentioned, the law provides a means whereby the application of the amendment may be

extended for not to exceed one year; we believe that, for the present, this industry undoubtedly has enough information to demonstrate that, under certain specifications, such an extension should be authorized without any undue risk to the health of consumers. The procedures for requesting such extensions were outlined in the *Federal Register* of December 31, 1959, and reprints of this may be obtained for the asking from Washington or from any of our 17 district offices.

We have, over the years, given prior sanctions to a number of uses of fatty acids and their derivatives in the preparation of packaging materials for food products. There is no disposition on our part to withdraw these sanctions now, but as we get more information about the basic problems, we will want to review all of these. In the meantime, we can only recommend that, in operating under one of these sanctions, you use only fatty-acid products having specifications comparable to those which are established as suitable for those used as direct additives to food.

While we do not think that the problems here are insurmountable, we do not for a moment believe that the problem should be minimized. It is a large one and, in our opinion, will require at least the combined efforts of the fatty-acid industry and the Food and Drug Administration to achieve a solution in the form of specifications for food-additives materials. We would like to suggest that a cooperative arrangement be made between your organization and ours for a study of the raw materials which go into food fat-processing plants and the various incidental chemical additives used at various points in the process as, for example, in the steam, the various types of operations, distillations, crystallizations, residue feedbacks, and the final materials.

A step in this direction is illustrated by the appointment of the special technical committee of the Fatty Acid Producers' Council which met with our technical people on January 7, 1960. We hope this committee will continue to be active and will continue to work with our people in the solution of this problem.

I would suggest that the first step would be to try to agree on interim specifications which could be the basis for the extension requests mentioned earlier. Obviously, these will not present the final answer, but a real stopgap is paramount now.

Commissioner Larrick has asked that I give you his assurance that our people will do everything possible to assist in the solution of these very real problems. **[The End]**

Foreign Law Comment

By JULIUS G. ZIMMERMAN

International Developments

The international scene in the field of food legislation continues to be dominated by the topic "food additives." The recent developments in the United States have been widely commented upon abroad, but it is still an open question in many countries to what extent our official "white lists" will be followed. The subject of food law in general and/or food additives in particular will be discussed in at least three important international meetings this year:

(1) The Fifth International Congress on Nutrition, which is to be held in Washington September 1-7, 1960 (secretariat: 9650 Wisconsin Avenue, Washington, D. C.).

(2) The Pure Food Centenary in Britain, in commemoration of the hundredth anniversary of the enactment by the British Parliament of an "Act for preventing the Adulteration of Articles of Food and Drink," which was the first general law covering the subject ever enacted in any country in the world and which inaugurated the age of modern food legislation. The British government, in cooperation with the leading British scientific societies and the British food and chemical industries, is organizing a special international conference to celebrate and commemorate this historic event appropriately. The conference is scheduled to take place in London September 20-23, 1960, and will consist of an official reception by the British Government, a pure-food exhibition and a number of meetings with lectures by members of the government and leading experts in the field. The list of speakers also includes Commissioner George P. Larrick (United States), C. A. Morrell (Canada), and Norman C. Wright, deputy director-general of the Food and Agricultural Organization of the United Nations. William T. Brady, chairman of the Food Law

Institute, is one of the vice-presidents of honor. This will assure a broad discussion of pure food and pure-food legislation on an international level (secretariat: The Pure Food Centenary, 14 Belgrave Square, London S. W. 1).

(3) The Sixth International Symposium on Food Additives, which is organized under the joint sponsorship of the International Commission for Agricultural Industries (CIIA) and the Permanent International Bureau of Analytical Chemistry of Human and Animal Food (PIBAC), which will be held in Madrid October 10-16, 1960. This meeting will continue to discuss the subject of food additives and also the question of international food standards which are presently being drafted by the European Food Code Council (secretariat of CIIA: 18 Avenue de Villars, Paris VII, France).

New Legislation

In Europe, two countries have recently promulgated important food laws:

Belgium.—The Belgian Government published in the official gazette (*Moniteur Belge*) of December 3, 1959, a royal decree on food colors, dated October 27, 1959, the purpose of which is to regulate the manufacture and sale of "food colors." It lists about 40 authorized colors and also permits the use of certain mixtures and certain harmless colors extracted from food products. The traffic in all other food colors is prohibited. Anyone who wishes to manufacture, import or sell any authorized colors has to register them with the food-inspection department and the label of the package has to bear the legend "food color" and the registration number. The new decree abrogates the old legislation on that subject and it will probably be implemented by further regulations on the use of food colors by the food industry.

Germany.—The "foreign substances" amendment to the German Food Law of 1936 was published December 23, 1958, but only became effective one year later, on December 23, 1959. As of that date the use of all "foreign substances" and all "technical aid substances" was made illegal, with the exception of only those the use of which is specifically authorized by law or regulation. Article 3 of the amendment provided that all regulations issued, as well as special exemptions granted by special executive rulings under the old law, with a bearing on "foreign substances" would become inoperative December 23, 1959, with the exception of the following regulations and laws listed in

Article 6 of the amendment, which remained temporarily in full force and effect until specifically abrogated:

(1) Regulation on artificial honey (March 21, 1930);

(2) Regulation on coffee (May 10, 1939);

(3) Regulation on coffee substitutes and additives (May 10, 1930);

(4) Regulation on enforcement of the wine law (July 16, 1932);

(5) Regulation on cocoa and cocoa products (July 15, 1933);

(6) Law on the use of salts of nitric acid in the food trade (June 19, 1934);

(7) Regulation on table waters (November 12, 1934);

(8) Regulation on caffeine-containing refreshing beverages (June 24, 1938);

(9) Regulations on trading in sweetening agents (February 27, 1939);

(10) Regulation on improper additions to, and treatment of, meat (October 31, 1940);

(11) Regulation on cheeses and cheese products (June 2, 1951);

(12) Law on excise taxes for beer, as published March 14, 1952;

(13) Regulation on the chemical treatment of flour and on foods and doughs of all sorts prepared with flour (December 27, 1956);

(14) Law on excise taxes for tobacco of May 6, 1953, as amended October 10, 1957;

(15) Law on prevention of contagious diseases (June 30, 1900), and regulations issued thereunder.

Supplementing these older laws and regulations the German government promulgated, with the approval of the *Bundesrat* (upper chamber of parliament), one new regulation under the meat inspection act of October 29, 1940, and 11 regulations under the "foreign substances" amendment, which were published in the *Bundesgesetzblatt* (*Federal Gazette*) December 22, 1959, and most of which became effective December 23, 1959:

(16) Regulation on improper additions to, and treatment of, meat (December 18, 1959), issued under the meat inspection act of October 29, 1940, replacing the regulation listed above under (10);

(17) Regulation on meat and meat products of December 19, 1959, which will become effective May 1, 1960;

(18) Regulation on tobacco and tobacco products (December 19, 1959);

(19) Regulation on the use of "foreign substances" for protection against microbial spoilage of foods (regulation on preservatives of December 19, 1959);

(20) Regulation on the use of "foreign substances" in foods (general regulation on foreign substances) of December 19, 1959;

(21) Regulation on the use of "foreign substances" in dietetic foods (December 19, 1959), expires automatically December 31, 1961;

(22) Regulations on essences and beverage bases (December 19, 1959);

(23) Regulation on the use of "foreign substances" for the treatment of fruits and fruit products (December 19, 1959);

(24) Regulation on the use of "foreign substances" in the preparation of chewing gum (December 19, 1959);

(25) Regulation on the use of "foreign substances" for the coloring of food (regulation on food colors) of December 19, 1959;

(26) Regulation on the treatment of foods with electron-, gamma-, and X-rays, or ultraviolet rays (December 19, 1959);

(27) Regulation on the use of "foreign substances" for the treatment of drinking water (December 19, 1959).

For the proper legal appraisal of this material it is necessary to keep in mind the definitions of "foreign substances" and "technical-aid substances" of the German Law of December 21, 1958, which amended the basic food law.

Article 4a(2):

The term "foreign substances" within the meaning of this law applies to substances which qualify as food in accordance with the definition of Article 1 and which do not contain any digestible carbohydrates, digestible fats, digestible albumen, and which do not naturally contain any vitamins, provitamins, aromatic, or flavoring substances; or where such content is not controlling for their use as food.

Article 4b(3):

Technical-aid substances are substances which are used in connection with the obtaining, manufacture, or preparation of food but which are not intended for consumption.

In other words, not every "food additive," including food colors, is necessarily a "foreign substance" as defined above. If it is not a "foreign substance," it is a regular "food" and is not subject to the special rules laid down by the amendment of December 21, 1958.

New Publications

Everyman's United Nations (Sixth Edition, 1959) was published recently by the Office of Public Information of the United Nations in New York. This is the first revision of the book since 1956, and it gives in 605 pages an up-to-date description of the general setup and the activities of the United Nations and its related agencies. Of particular interest for the food and drug lawyer are the chapters on the international control of narcotic drugs (pages 316-322), the World Health Organization (WHO) (pages 480-488) and the Food and Agricultural Organization (FAO) (pages 462-471), even though they are not detailed enough to answer all the questions about the technical work of the various expert committees and their publications. A detailed bibliography of all these publications can be obtained from the International Documents Service of Columbia University Press, New York 27, New York.

Food Additive Control in Canada is a 37-page booklet which appeared as the first of a series on food-additive control published by the FAO in Rome in 1959. It was written by L. I. Pugsley of the Food and Drug Directorate in Ottawa, Canada, and gives a comprehensive survey of this subject matter with a detailed list of legislation and sources, and a bibliography of Canadian literature on food additives.

Another publication which is an almost indispensable reference book for all those engaged in international research problems is the seventh edition (1958-1959) of the *Yearbook of International Organizations*, published in Brussels by the Union of International Associations. It contains essential data on 1209 international organizations (149 governmental and 1060 nongovernmental). But its most valuable feature is the elaborate indexes in English and in French, which cover key words (subject index), initials (abbreviations of the full names in English and French), and a geographical listing. Without such indexing, it would be very difficult to find out that WHO and OMS are the English and French abbreviations, respectively, for the World Health Organization (*Organisation Mondiale de la Santé*), and that the initials OAA are the French abbreviation for the Food and Agriculture Organization (FAO). A great deal of confusion in international research and reporting could be avoided if these technicalities of terminology were more widely known.

WASHINGTON—Continued from page 212

In the Department of Health, Education, and Welfare

Honor Awards Ceremony.—Secretary Arthur S. Flemming today presented 64 honor awards to outstanding employees of the Department of Health, Education, and Welfare at its ninth annual honor awards ceremony.

Four employees received distinguished service awards and 49 received superior service awards. Seven groups received unit citations for superior service. A joint citation was given to two employees. The Food and Drug Administration and the Office of Education received Secretary's special citations. The fifth annual Oveta Culp Hobby Award was given to an employee selected from those who received the superior service award.

In addition, length-of-service awards went to 30 employees who had completed 40 years of service with the United States Government during 1959.

The Oveta Culp Hobby Award was presented to J. Hiram Chappell "for pioneering and developing, through selfless devotion, imagination, and painstaking execution, a national program for the rehabilitation of blind people in agricultural pursuits." Mr. Chappell, who is Social Administration Specialist for Rural Training in the Office of Vocational Rehabilitation, also received a superior service award. The Oveta Culp Hobby Award consists of an engraved certificate and $200. The first Secretary of Health, Education, and Welfare established a fund for this annual award, to be given to an outstanding employee selected from those receiving distinguished and superior service awards.

Receiving distiguished service awards, the highest honor bestowed by the Department, were:

Lawrence G. Derthick, Ph. D., Commissioner of Education, Office of Education, Washington, D. C.

Rall I. Grigsby, Assistant Commissioner for School Assistance, Office of Education, Washington, D. C.

James F. Kelly, Director, Office of Financial Management, Office of Administration, Office of the Secretary, Washington, D. C.

G. Burroughs Mider, M. D., Associate Director in Charge of Research, National Cancer Institute, National Institutes of Health, Public Health Service, Bethesda, Maryland.

Those receiving superior service awards were:

Food and Drug Administration:

Lessel L. Ramsey, Chief, Food Additives Branch, Division of Food, Bureau of Biological and Physical Sciences, Washington, D. C.

Office of Education:

Henry H. Armsby, Chief for Engineering Education, Division of Higher Education, Washington, D. C.

Ward P. Beard, Assistant Director for State Plans and Grants, Division of Vocational Education, Washington, D. C.

Ernest V. Hollis, Ph. D., Director, College and University Administration Branch, Division of Higher Education, Washington, D. C.

Arno Jewett, Ph. D., Specialist for Secondary-School Language Arts, Di-

vision of State and Local School Systems, Washington, D. C.

Gertrude M. Lewis, Ph. D., Specialist for Upper Grades, Division of State and Local School Systems, Washington, D. C.

Wayne O. Reed, Ph. D., Deputy Commissioner of Education, Washington, D. C.

Fredrika M. Tandler, Ph. D., Assistant Director, International Educational Relations Branch, Division of International Education, Washington, D. C.

Office of the Secretary:

Bernice L. Bernstein, Regional Attorney, Office of the General Counsel, Region II, New York, New York.

Kent F. Bradbury, Regional Merit System Representative, Office of Field Administration, Region III, Charlottesville, Virginia.

J. Wendell Gray, Chief, Division of Surplus Property Utilization, Office of Field Administration, Washington, D. C.

Daniel O. Mathewson, Budget Analyst, Office of Financial Management, Division of Budget, Office of Administration, Washington, D. C.

Elmer W. Smith, Budget Analyst, Office of Financial Management, Office of Administration, Washington, D. C.

Florence H. Stover, Administrative Assistant, Office of Financial Management, Office of Administration, Washington, D. C.

Edwin Yourman, Assistant General Counsel, Welfare and Education Division, Office of the General Counsel, Washington, D. C.

Office of Vocational Rehabilitation:

J. Hiram Chappell, Social Administration Specialist (Vocational Rehabilitation) Rural Training, Division of Services to the Blind, Office of the Assistant Director for State Program Operations, Washington, D. C.

Samuel E. Martz, Assistant Director for Management Services, Washington, D. C.

Marian L. McVeigh, Associate Regional Representative, Region II, New York, New York.

Robert E. Thomas, Associate Regional Representative, Region VII, Dallas, Texas.

Public Health Service:

William B. Bellamy, Public Buildings Superintendent, U. S. Public Health Service Hospital, Bureau of Medical Services, San Francisco, California.

William Bridge Cooke, Ph. D., Mycologist, Robert A. Taft Sanitary Engineering Center, Bureau of State Services, Cincinnati, Ohio.

Carl C. Dauer, M. D., Medical Adviser, National Office of Vital Statistics, Bureau of State Services, Washington, D. C.

Wilbur E. Deacon, Ph. D., Microbiologist, Venereal Disease Branch, Communicable Disease Centers, Bureau of State Services, Chamblee, Georgia.

Joseph E. Devery, Executive Housekeeper, U. S. Public Health Service Hospital, Bureau of Medical Services, San Francisco, California.

Bessie D. Fisk, Medical and X-Ray Technician, Public Health Service Indian Hospital, Bureau of Medical Services, Rapid City, South Dakota.

Helen L. Johnston, Public Health Adviser, Division of General Health Services, Bureau of State Services, Washington, D. C.

Harry J. Wiener, Visual Information Officer, Office of the Chief, Bureau of Medical Services, Washington, D. C.

Robert T. Williams, Executive Officer, Division of Special Health Services, Bureau of State Services, Washington, D. C.

J. Franklin Yeager, Ph. D., Chief, Grants and Training Branch, National Heart Institute, National Institutes of Health, Bethesda, Maryland.

Saint Elizabeths Hospital:

David W. Harris, M. D., Clinical Director Branch No. 1, Division of Medical Services, Washington, D. C.

James D. Solomon, Ph. D., Director of the Laboratory Branch, Division of Medical Services, Washington, D. C.

Social Security Administration:

Mildred Arnold, Director, Division of Social Services, Children's Bureau, Washington, D. C.

Irma Barrera, Claims Representative, District Office, Bureau of Old-Age and Survivors Insurance, San Antonio, Texas.

Elisabeth D. Barton, Assistant to the Chief for Cooperative Planning, Children's Bureau, Washington, D. C.

Philip Bonn, Head, Visual Services Section, Division of Reports, Children's Bureau, Washington, D. C.

George W. Boyd, Chief, Division of Program Services, Bureau of Federal Credit Unions, Washington, D. C.

Bess J. Craig, Regional Child Welfare Representative, Children's Bureau, Region V, Chicago, Illinois.

Charles J. Dafcik, Supervisory Management Analysis Officer, Division of Claims Control, Bureau of Old-Age and Survivors Insurance, Baltimore, Maryland.

Charles M. Erisman, Deputy Assistant Director, Division of Disability Operations, Bureau of Old-Age and Survivors Insurance, Baltimore, Maryland.

Vinson J. Gordon, Chief, Forms and Records Management Section, Division of Management Planning and Services, Bureau of Old-Age and Survivors Insurance, Baltimore, Maryland.

Dorothy Lally, Chief, International Service, Office of the Commissioner, Washington, D. C.

Ellsworth J. Listerman, Chief, Payment Center, Bureau of Old-Age and Survivors Insurance, Birmingham, Alabama.

Solomon S. Macks, Chief, Pay Roll Section, Fiscal Management Branch, Division of Management Planning and Services, Bureau of Old-Age and Survivors Insurance, Baltimore, Maryland.

James E. Marquis, Deputy Assistant Director, Division of Program Analysis, Bureau of Old-Age and Survivors Insurance, Baltimore, Maryland.

Ida C. Merriam, Director, Division of Program Research, Office of the Commissioner, Washington, D. C.

William Roemmich, M. D., Chief Medical Officer, Medical Consultant Staff, Division of Disability Operations, Bureau of Old-Age and Survivors Insurance, Baltimore, Maryland.

Ernest W. Tallman, Regional Representative, Bureau of Old-Age and Survivors Insurance, Region IX, San Francisco, California.

Edward N. Watman, Chief, Coverage Branch, Division of Claims Policy, Bureau of Old-Age and Survivors Insurance, Baltimore, Maryland.

Irwin Wolkstein, Assistant Chief, Coverage and Disability Planning Branch, Division of Program Analysis, Bureau of Old-Age and Survivors Insurance, Baltimore, Maryland.

The seven units which received superior service awards were: Detroit District Building Team, Food and Drug Administration, Washington, D. C.; Methods and Operations Research Group, Chemical and Microbiological Branch, Bureau of Biological and Physical Sciences, Food and Drug Administration, Washington, D. C.; Research Development Staff, Division of Nutrition, Bureau of Biological and Physical Sciences, Food and Drug Administration, Washington, D. C.; Budget Formulation and Execution Unit, Financial Management Branch, Bureau of State Services, Public Health Service, Washington, D. C.; Medical Technical Assistants, Federal Detention Headquarters, Bureau of Medical Services, Public Health Service, New York, New York;

Venereal Disease Research Laboratory, Communicable Disease Center, Bureau of State Services, Public Health Service, Chamblee, Georgia; and Staff Assigned to the Advisory Council on Public Assistance, Bureau of Public Assistance, Social Security Administration, Washington, D. C.

A joint citation was presented to Charles B. Lawrence, Jr., and Luther W. Stringham of the Program Analysis Staff, Office of Assistant to the Secretary (for Program Analysis) "for exceptionally meritorious service in conceiving and developing for executive and public use the two publications, *HEW Indicators* and *HEW Trends.*"

Miss Bertha S. Adkins, Under Secretary, presided at the honor awards ceremony, which was held in the auditorium of the Department of Health, Education, and Welfare. Music was furnished by the United States Army Orchestra.

In the Federal Trade Commission

Combining or Conspiring — Crab Fishermen.—A crab association and its officials and fishermen members are charged with unlawfully restraining competition in the crab industry through the use of coercion in a conspiracy to get nonmember crab fishermen to join the association. It is alleged that the association fixes prices paid by canners to members for their catch and has the actual power to monopolize all phases of the crab industry. (Issued April 7; released April 15, 1960.)—CCH TRADE REGULATION REPORTS ¶ 28,686.

Misrepresentation—Hearing Aids.—Two firms are prohibited from misrepresenting their hearing aids as buttonless, cordless and invisible. In the first instance, a consent order released April 8, 1960, forbids such claims unless the advertisements disclose with equal prominence that a plastic tube runs from the device and is attached to an ear mold fitted in the ear. The company must also stop claiming that its hearing aids are (1) invisible when worn, (2) hidden behind the ear or concealed within an eyeglass temple when there is a visible tube and (3) worn completely in the ear, unless this is true. In addition, it must not misrepresent the size of any hearing aid or claim that one of its hearing aids provides equally good hearing from all directions without disclosing that it is necessary to wear a hearing aid in each ear.

The order also dismisses four other charges in the complaint. One cannot be sustained and the others were based on distributors' advertisements for which the respondents are not responsible, the hearing examiner in the case said.

In the second instance, a consent order was released on April 12. The company had been charged in an FTC complaint issued April 2, 1959, with falsely advertising certain of its models in newspapers, magazines, and promotional matter furnished dealers.

The firm's president is joined in the order in his official capacity, but the complaint was dismissed against him in his individual capacity because "there is no proof to be adduced to bind him individually." The Commission amended the examiner's finding pertaining to this dismissal to conform with the language in the consent agreement.

Both agreements are for settlement purposes only and do not constitute admissions by the respondents that they have violated the law.—CCH TRADE REGULATION REPORTS ¶ 28,677, 28,679.

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